

# **2024 FDA-Human Foods Program, Retail Food Policy Update**

**Wendy Fanaselle  
November 14, 2024  
Burlington, VT**

**[RetailFoodPolicyTeam@fda.hhs.gov](mailto:RetailFoodPolicyTeam@fda.hhs.gov)**



Office of Retail Food Protection



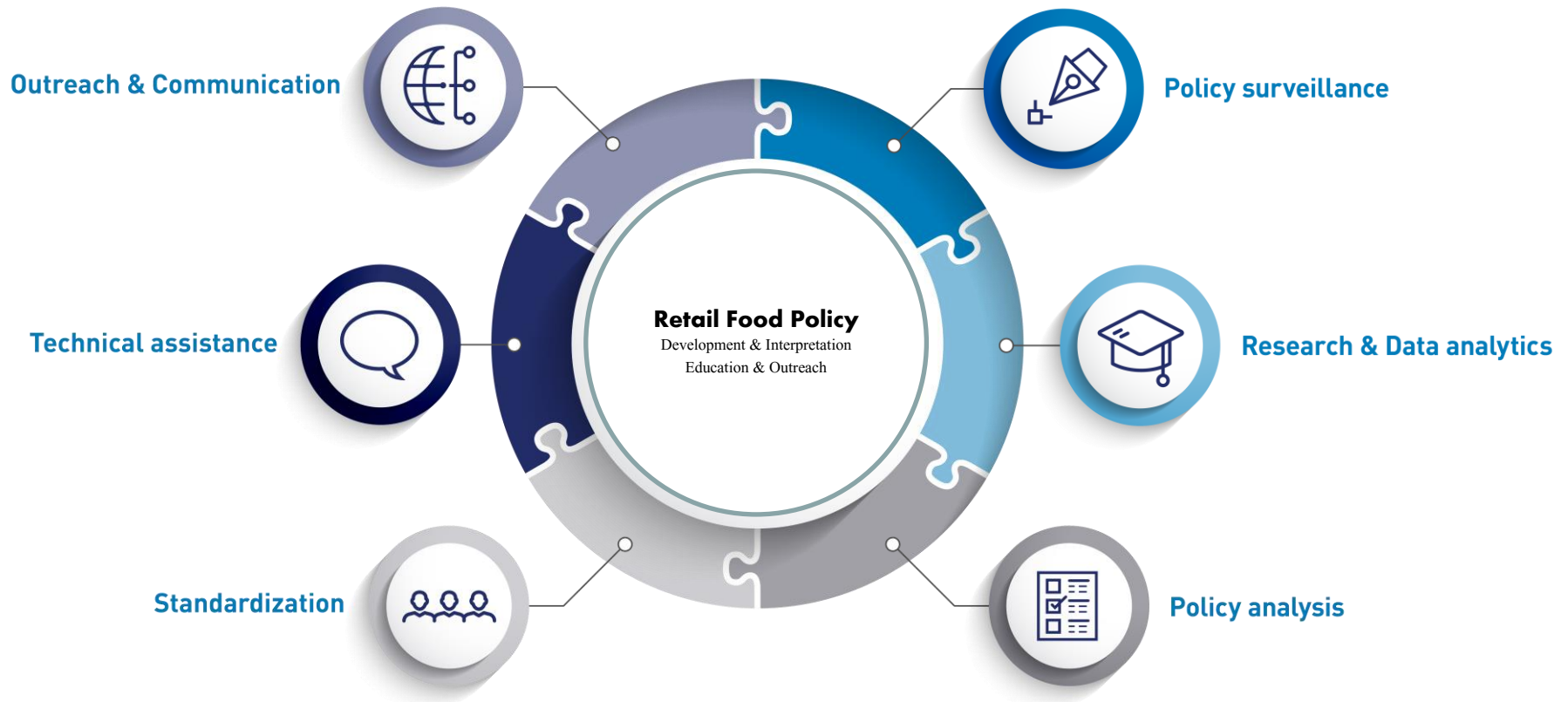
- Our Team
- Retail Food Policy Updates
  - CFP 2025*
  - Food Code Supplement*

# New Office/ New Name

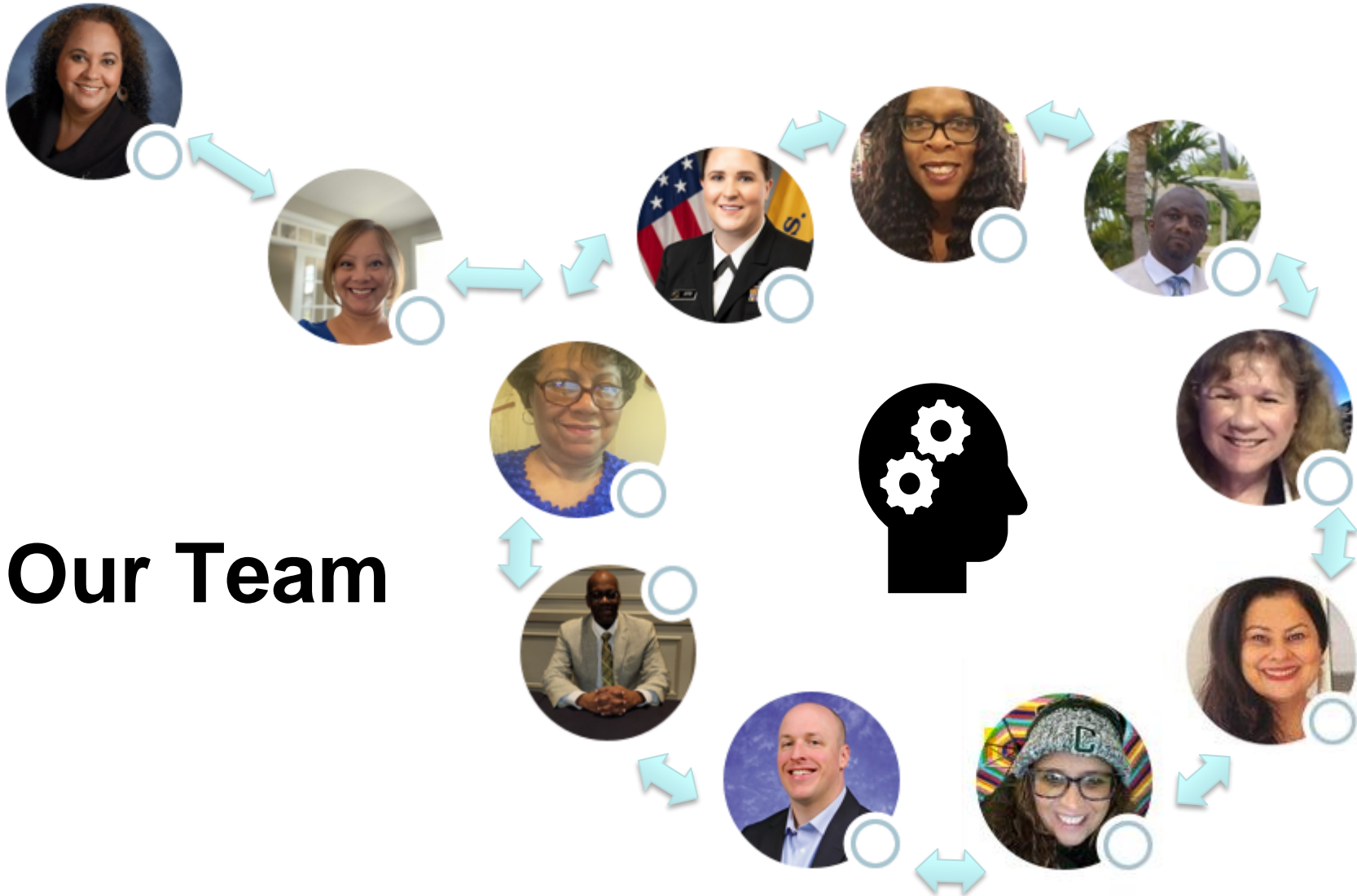


- Human Foods Program
- 
- Office of Integrated Food Safety System Partnerships (OIFSSP):
- 
- Office of Retail Food Protection (ORFP)
- 
- Division of Retail Food Protection Policy, Research, and Risk Assessment (DRFPPRA)

# Strategic Areas and Program Activities



# Strategic Areas and Program Activities



**Our Team**



## Voluntary National Retail Food Regulatory Program Standards



"Standards of Excellence for Continual Improvement"

*Developed and recommended by the U.S. Food and Drug Administration with input from federal, state, and local regulatory officials, industry trade associations, academics, and consumers.*

---

# 2022

---

U.S. Department of Health and Human Services

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
College Park, MD 20740

2022  
**Food Code**  
U.S. Food and Drug Administration

CELEBRATING  
**30**  
THIRTY YEARS

- **The Conference for Food Protection (CFP)**



- [www.foodprotect.org](http://www.foodprotect.org)

*Encourages democratic deliberations by government, industry, academic and consumer interests*

*Provide public health ratification such as a state-by-state vote by officially designated delegates*

*Next Meeting is in Denver, CO, March 24-28*

# CFP Issue Submission



Opens November 24, 2024 & closes December 2024

- An issue is a topic submitted for consideration to the Conference by any interested party which addresses an identified concern related
  - *Issue Pre- Submission Form*
  - *Terms and Conditions for Issue Submission*
  - *Issue Preparation & Review Process and Checklist*

For info on the submission process:

<https://www.foodprotect.org/about/issue-submission/>



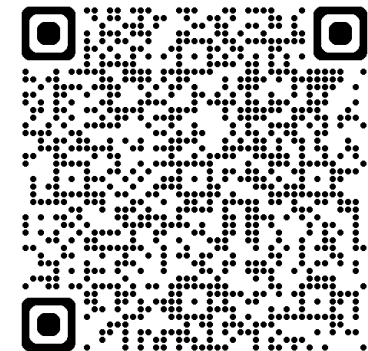


# 5 TIPS

to preparing policy recommendations for  
**RETAIL FOOD POLICY DEBATE**

INFORMATION AVAILABLE AT:

[5-TIPS WHEN PREPARING RECOMMENDED CHANGES](#)



Attempting to solve the nation's retail food safety challenges involves debate over the most effective, efficient, and feasible policy option to solve identified problems. Through our work in retail food policy analysis, we have identified five things individuals can do to prepare retail food policy recommendations for debate.

1

### Clearly define the problem that needs to be addressed

Public policy making is about problem solving. If no problem exists there is no need to offer a policy solution. Establishing policy to fix a nonexistent problem may lead to new problems and unintended consequences.

- Describe and provide evidence for the existence, size, and severity of the problem.

2

### Clearly describe the cause of the problem

Problem solving requires focusing on the underlying cause(s) of the problem.

- Provide the reasoning and evidence to support a link between the problem and cause.
- Anticipate that your reasoning and evidence will be challenged during debate.

3

### Clearly explain why the status quo is not addressing the problem

Recommendations to change policy assumes that the status quo is not working. Does structural, attitudinal, or gap inherency exist?

- Structural Inherency - a formal block (like a law)
- Attitudinal Inherency - an informal block (like perceptions or lack of awareness)
- Gap Inherency - existing solutions aren't doing enough to solve the problem

4

### Clearly present your recommended policy solution and explain why it should be preferred over possible alternatives

Provide the reasoning and evidence behind how and why your proposed solution will resolve the problem and why it is preferable over other alternatives and the status quo.

- What criteria did you use for comparison?
- Can a non-policy option address the problem?

5

### Clearly state the potential consequences of implementing the recommended policy solution

Describe the intended and unintended consequences (both material and social) of implementing your policy solution.

- Do the positive consequences outweigh the negative consequences?



### Anticipate stakeholder questions and concerns

Be prepared to address questions and concerns regarding areas of potential disagreement (clash points) with the claims, evidence, and assertions you have made. Clash points may involve facts, value, and/or policy.

Fact - assertion about what is and what isn't or what happened or didn't happen  
Value - assertion over what is appropriate or inappropriate; good or bad  
Policy - assertion about what we should do or what the policy should be

Retail Food Protection Policy Branch (DRFPPRR)

## SUPPLEMENTS TO THE 2022 FOOD CODE

April  
2023

CFP 2023 held in Houston, TX April 24-28  
*117 Issues deliberated*

June  
2023

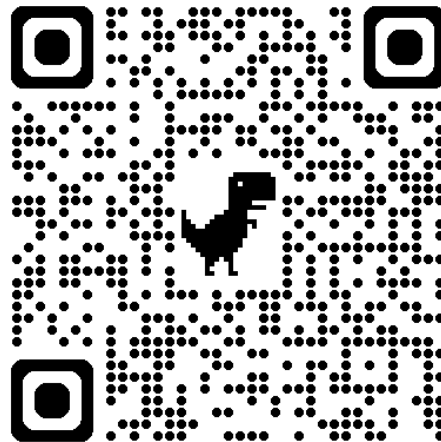
Letter sent to FDA containing 44 Recommendations Link: [2023 CFP Letter to FDA](#)  
*25 recommended changes to the Food Code or Annexes*

August  
2023

FDA sent response letter to CFP Link: [2023 FDA Letter to CFP](#)  
Highlights:

- Food Defense
- Active Managerial Control
- Food Safety Management Systems
- Disinfectants
- Reuseable Containers
- Program Standards Updates

# SUPPLEMENT TO THE 2022 FOOD CODE CHANGES



# Final Issue Recommendations and FDA Response to CFP



- We will present the final Issue recommendations for each topic
- If you are interested in the final Issue actions or response letter to CFP you can find them here:

[FDA Response Letter to CFP](#)

[Issue recommendations CI](#)

[Issue recommendations CII](#)

[Issue recommendations CIII](#)

# Summary of Change Language

## Amendatory Terms

- **Add** - means a new provision has been inserted in the Food Code.
- **Redesignate** - means to modify a Food Code provision by reformatting the text of the provision into a new structural nomenclature designation.
- **Remove** - means an existing provision is being taken out of the Food Code.
- **Revise** - means an existing Food Code provision is replaced in part, or in its entirety.

# **ACTIVE MANAGERIAL CONTROL AND FOOD SAFETY MANAGEMENT SYSTEMS**

CFP Issue 2023-II-043

# Issue Action and FDA Response



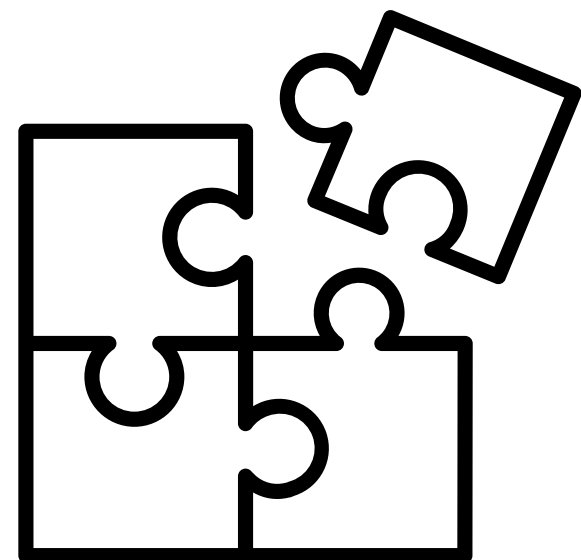
The Issue recommendations were:

- Add the definition of AMC (already in Annex 4) to §1-201.10
- Use the term “active managerial control” in § 2-103.11 Person In Charge (Duties)
- Replace term SOPs for FSMS in § 8-201.12 Contents of the Plans and Specifications
- Add the definition of FSMS (utilizing input from the committee) to § 1-201.10



# Key Concepts

- AMC becomes a defined term and incorporated in 1st paragraph of §2-103.11 Duties of the PIC
  - Emphasize ACTIVE Managerial
  
- FSMS becomes a defined term and appears in §8-201.12 Contents of the Plans and Specifications
  - SOP replaced by FSMS
  
- New §8-201.15 When an FSMS is Required
  - Grace period
  
- Reserve section §8-201.16 for contents of an FSMS
  - Review tools developed by the committee and others before development



# Active Managerial Control

- **New Defined Term**

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

- **§2-103.11 Person in Charge**

**2-103.11 Person in Charge**

The PERSON IN CHARGE shall maintain ACTIVE MANAGERIAL CONTROL of foodborne illness RISK factors by ensuring that:

Paragraphs (A)-(Q)....NO CHANGE

# Food Safety Management Systems



- **New Defined Term**

**“Food Safety Management System”**

**“Food Safety Management System”** means a specific set of actions taken by the EMPLOYEE to prevent the occurrence of foodborne illness RISK factors based on the type of operation, type of FOOD preparation, and FOODS prepared within the FOOD ESTABLISHMENT.

**“Food Safety Management System”** includes written procedures, training plans, and monitoring records to control specific operational steps in a FOOD ESTABLISHMENT that contribute to foodborne illness.

# §8-201.12 Contents of the Plans and Specifications

- Revised ¶8-201.12(E) to replace term Standard Procedures with Food Safety Management System

## §8-201.12 Contents of the Plans and Specifications.

The plans and specifications for a FOOD ESTABLISHMENT, including a FOOD ESTABLISHMENT specified under § 8-201.13, shall include, as required by the REGULATORY AUTHORITY based on the type of operation, type of FOOD preparation, and FOODS prepared, the following information to demonstrate conformance with Code provisions:

Paragraphs (A)-(D)....NO CHANGE...

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

Paragraph (F)... NO CHANGE...

# New §8-201.15 When a Food Safety Management System is Required



(A) Within 4 years of the REGULATORY AUTHORITY'S adoption of this Code, a written FOOD SAFETY MANAGEMENT SYSTEM shall be:

- (1) Developed and maintained to ensure compliance with requirements of this Code as specified in 2-103.11.<sup>Pf</sup>
- (2) Implemented in the FOOD ESTABLISHMENT during all hours of operation,<sup>Pf</sup> and
- (3) Made available to the REGULATORY AUTHORITY upon request.<sup>Pf</sup>

*(B) This section does not apply to certain types of FOOD ESTABLISHMENTS deemed by the REGULATORY AUTHORITY to pose minimal RISK of causing, or contributing to, foodborne illness based on the nature of the operation and extent of the FOOD preparation.*



# Reserved §8-201.16 Contents of a Food Safety Management System

- **§8-201.16 Contents of a FOOD SAFETY MANAGEMENT SYSTEM.**

RESERVED.

- Reserving this provision will allow time for the CFP's Food Safety Management Systems Committee to develop the contents for a food safety management system which will inform a permit applicant or permit holder the components that must be included in their "Food Safety Management System".

# Regulator Call to Action



# Regulator Actions to Foster FSMS



talk to operators about their procedures



learn about how they train their staff



ask how they ensure staff follow their procedures



discuss corrective actions



provide feedback and resources





# DISINFECTANTS

CFP Issue 2023-III-015



# Issue Action and FDA Response

The Issue recommendations were:

- Define the term “Disinfection”
- Include the term where appropriate throughout the Code
- Create a new Part, Subpart and accompanying sections that model the sanitizer provisions in Ch 4
- Update corresponding Annexes (PHRs and Guide 3B Marking Instructions)

# Key Concepts

- Defined the term “Disinfection”
- Created a NEW PART, Subpart and Section series to address disinfection
- Amended certain provisions in Ch4 and Ch7 and corresponding Annexes to include disinfection where appropriate

# Disinfectants

- **New Defined Term**

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

- **Revised Defined Term**

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

(1) Cleaners, SANITIZERS and DISINFECTANTS which include

- cleaning, SANITIZING and DISINFECTION agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;

(2) Pesticides, *except* SANITIZERS and DISINFECTANTS which

- include substances such as insecticides and rodenticides;

(3)-(5)....NO CHANGE



# Disinfectants

- **§4-302.14 Sanitizing and Disinfecting Solutions, Testing Devices**

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

(B) A test kit or other device that accurately measure the concentration of DISINFECTING solutions shall be provided.<sup>Pf</sup>

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

(A) Concentration of the SANITIZING or DISINFECTING solution shall be accurately determined by using a test kit or other device.<sup>Pf</sup>

(B) A test kit, used to determine the concentration of a SANITIZING or DISINFECTING solution shall be used in accordance with the manufacturer's label instructions.

- **§7-102.11 Common Name**

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



# Disinfectants – NEW Part 4-10

## Disinfection of Equipment and Utensils

- **4-1001 Objective**

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

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

- **4-1002 Frequency**

- **§4-1002.11 Disinfectant Use**

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

- (A) When contaminated with vomitus, fecal matter, blood, or any other bodily fluid that can lead to disease transmission;<sup>P</sup> or

- (B) During a FOODBORNE DISEASE OUTBREAK OR IMMINENT HEALTH HAZARD.<sup>P</sup>

- **4-1003 Methods**

- **§ 4-1003.11 Chemical**

- (A) FOOD-CONTACT SURFACES and non-FOOD CONTACT SURFACES shall be DISINFECTED in accordance with the EPA-registered label use directions.<sup>P</sup>

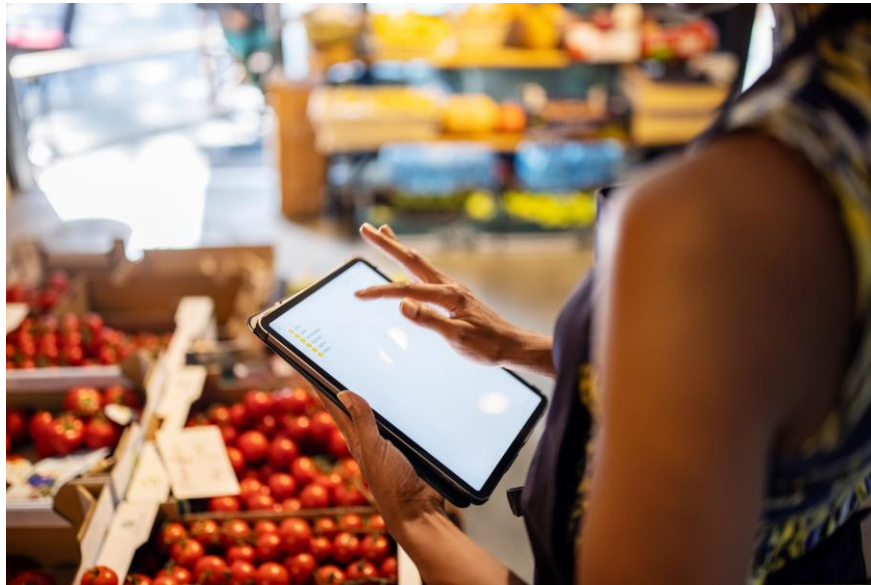
- (B) DISINFECTANTS applied to a FOOD-CONTACT SURFACE shall be rinsed with potable water, unless otherwise specified on the EPA-registered label use directions.<sup>P</sup>



# Disinfectants

## Corresponding Annex changes to reflect addition of disinfection:

- **Created new Annex 3 PHRs for each new section**
  - §4-1001.11 Food-Contact Surfaces, Non-Food-Contact Surfaces, and Utensils.
  - § 4-1002.11 Disinfectant Use
  - § 4-1003.11 Chemical
- **Updates to Annex 7 Guide 3B (to align w/ corresponding codified section updates)**
  - Item #16
  - Item #28 (add in term disinfectant)
  - Item #48 (corresponding updates from §§4-302.14 & 4-501.116)
- **Inspection Form – Item #16**
  - To include the term “Disinfectant”



# FOOD DEFENSE

CFP Issue 2023-II-039





# Issue Action and FDA Response

The Issue recommendations were:

- Define the term “Food Defense”
- Add new paragraph (18) to Demonstration of Knowledge provision
- Add new paragraph (R) to PIC Duties

# Key Concepts



- Broadened the scope of the Food Code to include Food Defense
- Added New Definition
- Added concepts of Food Defense in Chapter 2 Demonstration and PIC duties with corresponding Annex updates

# Food Defense

- **Preface**
  - Updated Part 3. Public Health and Consumer Expectation to include Food Defense concept
- **New Defined Term**

“**Food Defense**” is the effort to protect food from acts of intentional adulteration or tampering.
- **Ch 2 Demonstration – NEW ¶2-102.11(C)(18)**

Explaining steps that are taken to prevent intentional ADULTERATION by CONSUMERS, EMPLOYEES, or other PERSONS including monitoring operations, ingredients, supplies, and finished products for unusual or suspicious activities, or other FOOD defense activities.

# Food Defense



- **PIC Duties – New ¶2-103.11(R)**

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

- **Annex 2, Part 4 Food Defense Guidance from Farm to Table**

- Amended this section throughout to fix outdated and broken links and provide the most updated resources from FDA and USDA.

- **Annex 3 PHRs and Annex 7 Guide 3B**

- Amended PHR for §1-201.10 and §2-103.11 to include new language addressing the addition food defense
- Corresponding changes in Annex 7 Guide 3B Item #1



# REFILLING RETURNABLES

CFP Issue 2023-III-012





# Issue Action and FDA Response

- Expand the use of reusable containers beyond non-TCS food
- Determine minimum requirements for acceptability of containers to be refilled
- Determine how the containers should be handled to prevent cross-contamination
- Clarify that these requirements should be applied to third-party vendors of these containers

# Key Concepts

- Enhanced Allowance for Refilling Reusable Containers
- Amended applicable Chapter 3 provisions
- Amended applicable Annex 2 references
- Amended applicable Annex 3 public health reasoning
- Amended marking instructions (guide 3-B)

# §3-304.17 Refilling Returnables



(A) Containers may be refilled with FOOD either by a FOOD EMPLOYEE or the CONSUMER, if:

(1) The container is designed and constructed for multiuse in accordance with the requirements specified under 4-101.11, 4-201.112, and 4-202.11 of this Code, and

(2) The container is cleaned and sanitized following procedures as specified under 4-601.11, 4-602.11, 4-701.10, 4-702.11 and 4-703.11 of this Code prior to refilling, and,

(3) The container is visually inspected by a FOOD EMPLOYEE to verify that the container, as returned, meets the requirements specified prior to use. <sup>Pf</sup>

(B) Except as specified in ¶¶ (D) of this section, containers refilled in a FOOD ESTABLISHMENT shall be refilled so that:

(1) The container is refilled in a contamination-free transfer process; <sup>Pf</sup>

(2) The container is handled to prevent direct contact with FOOD-CONTACT SURFACES; and <sup>Pf</sup>

(3) FOOD-CONTACT SURFACES are cleaned as specified under Part 4-6 and sanitized as specified under Part 4-7 of this Code by a FOOD EMPLOYEE. <sup>Pf</sup>

(C) Containers returned to a FOOD ESTABLISHMENT for cleaning and refilling in a regulated FOOD PROCESSING PLANT shall not be refilled at a FOOD ESTABLISHMENT.

(D) CONSUMER-owned containers that are not FOOD-specific may be filled at a water VENDING MACHINE or system.



# Annex 2 Changes for §3-304.17



- **Removed outdated 1985 reference (Annex 2)** Food and Drug Administration, 1985. Food Protection – Refilling of take-home beverage containers (8/29/85). Retail Food Protection Program Information Manual.
- **Added supporting document (Annex 2)** link to CFP developed Refilling Reusable Container Guide (CFP Issue 2023-III-010) [Guidance Document for the Safe Reuse of Containers | Conference-Developed Guides and Documents | Conference for Food Protection](#)

## Annex 3 PHR Updates for §3-304.17

- Provides guidance on minimum standards to protect food safety when refillable containers are used
- Allows wider and more standardized use of reusable containers.

# Guide 3-B Marking Instruction Changes for 3-304.17 Refilling Returnables



## **47. Food and non-food-contact surfaces cleanable, properly designed, constructed and used**

Amended to add “Refillable containers must be cleaned, sanitized, and inspected prior to filling, and must not contaminate the premises.”

3-304.17 Refilling Returnables (Pf)(C)

# EMPLOYEE HEALTH

CFP Issue 2023-III-030

## CFP ISSUE: AMEND FOOD CODE BY ADDING LABORATORY METHODS FOR REINSTATING ILL FOOD EMPLOYEES

- **Amend** 2-201.13(E)(1); 2-201.13(F)(1); and 2-201.13(G)(1) to allow the use of culture independent diagnostic test (CIDTs) results, such as molecular or enzyme-based methods
- Culture-based tests are still used but largely being replaced by CIDTs and produce accepted results

### FDA Response:

**Replaced mandatory stool culture tests in 2-201.13 (E)(1), 2-201.13(F)(1) and 2-201.13(G)(1) with “2 consecutive negative laboratory test results from a validated test obtained from stool specimens”:**

***Note: Reinstatement for diagnosed employees with Shigellosis, STEC, and Salmonellosis are the only pathogens updated because they are the only listed illnesses requiring stool culture test results for reinstatement***



# Example: Updated Criteria for Reinstatement of Diagnosed Ill Food Employees with illness from STEC, *Shigella spp.*, or Nontyphoidal *Salmonella*:

## ***Shigella spp. Diagnosis - Removing Exclusion or Restriction***

**2-201.13 (E)** Reinstatement a FOOD EMPLOYEE who was EXCLUDED as specified under Subparagraphs 2-201.12(A)(2) or (E)(1) or who was RESTRICTED under Subparagraph 2-201.12(E)(2) if the PERSON IN CHARGE obtains APPROVAL from the REGULATORY AUTHORITY and one of the following conditions is met:

**(1)** The EXCLUDED or RESTRICTED FOOD EMPLOYEE provides to the PERSON IN CHARGE written medical documentation from a HEALTH PRACTITIONER stating that the FOOD EMPLOYEE is free of a *Shigella spp.* infection based on 2 consecutive negative laboratory test results from a validated test, using a laboratory accredited or certified to handle clinical specimens and obtained from stool specimens that are taken:

(a) Not earlier than 48 hours after discontinuance of antibiotics, <sup>P</sup> and

(b) At least 24 hours apart; <sup>P</sup>

# WATER-BASED FIRE PROTECTION SYSTEM

CFP Issue 2023-I-024

# Issue Action and FDA Response



- CFP Issue : 2023-I-024 submitted by National Fire Sprinkler Association (NFSA) to revise the Food Code language referencing "leaking fire sprinkler heads" rejected at Council and extracted during Assembly.
- August 2023 - CFP Executive Board created Ad Hoc Committee to discuss Issue with Submitter and representative CFP membership
- April 2024 - Ad Hoc committee submitted recommendations for FDA to work with NFSA to determine accurate language referring to fire sprinkler/systems in §§§'s 3-305.12, 4-401.11, 4-903.12 and any other references
- NSFA/FDA worked together to update language where needed within the Code



# Key Concepts



- Updates **provide an aligned definition** for WATER-BASED FIRE PROTECTION SYSTEMS used by the International Fire Code (IFC) and NFPA 1 Fire Code
- **Replaced language** specific to "leaking sprinkler heads" in §§§'s 3-305.12, 4-401.11, & 4-903.12 with new defined term
- **Updated Annex 2 & 3** references under §6-202.15 Outer Openings, Protected to reflect the newest edition of NFPA 101 Life Safety Code

# 1-201.10(B) Water-based Fire Protection System



- **New Defined Term**

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

# §3-305.12 Food Storage, Prohibited Areas

FOOD may not be stored:

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



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

(A) Except as specified in ¶ (B) of this section, EQUIPMENT, a cabinet used for the storage of FOOD, or a cabinet that is used to store cleaned and SANITIZED EQUIPMENT, UTENSILS, laundered LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES may not be located:

- (1) In locker rooms;
- (2) In toilet rooms; <sup>Pf</sup>
- (3) In garbage rooms;
- (4) In mechanical rooms;
- (5) Under sewer lines that are not shielded to intercept potential drips;
- (6) Under leaking or where water is condensed on pipes, tubes, or hoses, including plumbing, heating, air conditioning and WATER-BASED FIRE PROTECTION SYSTEMS.
- (7) Under open stairwells; or
- (8) Under other sources of contamination.

# §4-903.12

# Prohibitions

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

- (1) In locker rooms;
- (2) In toilet rooms; <sup>Pf</sup>
- (3) In garbage rooms;
- (4) In mechanical rooms;
- (5) Under sewer lines that are not shielded to intercept potential drips;
- (6) Under leaking or where water is condensed on pipes, tubes, or hoses, including plumbing, heating, air conditioning and WATER-BASED FIRE PROTECTION SYSTEMS.
- (7) Under open stairwells; or
- (8) Under other sources of contamination.

*(B) Laundered LINENS and SINGLE-SERVICE and SINGLE-USE ARTICLES that are PACKAGED or in a facility such as a cabinet may be stored in a locker room.*

# REDUCED OXYGEN PACKAGING

Editorial change and CFP Issue 2023-III-023

# §3-501.13 Thawing (ROP of Fish)



- **Risk Designation QA** of §3-501.13 Thawing
- **Aligned ¶3-501.13(E)** with other ¶'s in the section
- **Revised risk designation** from CORE to Priority Foundation

(E) REDUCED OXYGEN PACKAGED FISH that bears a label indicating that it is to be kept frozen until time of use shall be removed from the reduced oxygen environment:

- (1) Prior to its thawing under refrigeration as specified in ¶(A) of this section **Pf.**; or
- (2) Prior to, or Immediately upon completion of, its thawing using procedures specified in ¶ (B) of this section. **Pf**

# ¶1-201.10(B) ROP Definition



- **CFP Issues 2023-III-023** recommended that FDA revise the definition of ROP, specifically sub¶ (2)(d) that defines cook chill packaging to replace the term “bags” with “packaging” and clarify intent
- **Revised definition in sub¶ (2)(d)**
  - (a)-(c)...NO CHANGE
  - (d) Cook chill PACKAGING, in which cooked FOOD is hot filled into impermeable **PACKAGING (such as a bag or film on trays)** that is then sealed or crimped closed. The **PACKAGED** FOOD is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychrotrophic pathogens: or
  - (e)...NO CHANGE
- **Corresponding updates** to the definition made throughout the Code where applicable



# **ANNEX 3 PHR - §2-501.11**

CFP Issue 2023-III-017

# Issue Action and FDA Response

- Update Annex 3 PHR for §2-501.11 Clean-up of Vomiting and Diarrheal Events, to:
  - address use of disinfectants and
  - ensure that the steps listed in developing a written plan reflect the order of actions in a plan
- FDA worked in conjunction with the committee, EPA and CDC to ensure concurrence on revised language
  - Amended Public Health Reasons for §2-501.11 Clean-up of Vomiting and Diarrheal Events to revise paragraph 6 to include reference to EPA-registered disinfectants and to revise paragraph 9 by rearranging bulleted list of items to consider when developing a written plan to ensure the steps listed reflect the order of actions covered by the plan

# ANNEX 3 PHR - §2-301.12

CFP Issue 2023-III-031



# Issue Action and FDA Response

- CFP recommended amending §6-301.11 to address cleaning and soap dispenser refilling requirements
- FDA agreed that more information on this is needed, but did not concur with the recommended codified amendment, and added the information to **Annex 3, §3-301.11 Preventing Contamination from Hands**
- **Amended Annex 3, Public Health Reasons for § 2-301.12 Cleaning Procedure** to add new information on the utility of soap as part of the handwashing procedure and information on the potential to contaminate hands if bulk soap dispensers are not properly cleaned and sanitized before refilling, as well as the risks involved with diluting handwashing soap beyond manufacturer's instructions when refilling.

# **ANNEX 3 PHR - §3-301.11**

CFP Issue 2023-I-017

# Issue Action and FDA Response



- CFP recommended adding an interpretation and language in Annex 3, Public Health Reasons, § 3-301.11 describing a double handwash procedure and the use of nail brushes
- FDA agreed to add language in Annex 3, Public Health Reasons, § 3-301.11(E) describing a double handwash
- Existing information on nail brush use for handwashing was moved from Annex 3, § 2-301.12 to § 3-301.11(E), since the CFP issue highlighted the failure to reach intended audience as part of Annex 3, § 2-301.12.

## **Amendment in Annex 3, Public Health Reasons, ¶3-301.11(E), Prior Approval for Food Employees to Touch Ready-to-Eat Food with Bare Hands:**

- “**Double handwashing**, as listed in ¶3-301.11(E)(6)(a), means handwashing 2 times (subsequentially) and at the same location immediately before handling RTE food with bare hands. This is in addition to other required handwashing events for food employees, such as after using the restroom. The double handwash technique involves washing and drying the hands at the handwashing sink as described in § 2-301.12, and immediately repeating the handwash procedure (including rinsing, applying a hand cleanser, scrubbing, rinsing, and drying the hands with an approved hand drying device) at the same handwashing sink.”

# ANNEX 6 FOOD PROCESSING CRITERIA

CFP Issue 2023-III-017

# Issue Action and FDA Response



- **CFP recommended** that FDA update the Code to include parameters around rice acidification that are consistent with the parameters in the committee generated guidance document entitled "Guidance Document for Retail Sushi HACCP Standardization"
- **Added new Section 4 titled: Acidification (Sushi Rice)**
  - Gives background and narrative around critical limits





# Any Questions?

**Please visit the FDA Retail Food Protection website at:**

**<http://www.fda.gov/RetailFoodProtection>**

**Contact FDA at the Food and Cosmetics Information  
Center (FCIC) using its inquiry web form link at:**

**<http://cfsan.force.com/Inquirypage>**

The End.

