

Food Safety Management Systems (FSMS): The Future of Retail Food Safety

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Background: Active Managerial Control (AMC)



- The purposeful incorporation of specific actions or procedures by industry management
- Attain control over foodborne illness risk factors
- Preventive rather than reactive
- Continuous system of monitoring and verification.

FSMS refers to a specific set of actions (e.g., procedures, training, and monitoring) to help achieve active managerial control.

Procedures (P): A defined set of actions adopted by food service management for accomplishing a task in a way that minimizes food safety risks. Procedures may be oral or written and include who, what, where, when, and how a task should be performed. The goal is to move toward complete, consistent, and primarily written procedures and may include topics such as when to wash your hands, how to set up a 3-compartment sink, how food temperatures are achieved and maintained/monitoring food temperatures.

Training (T): The process of management's informing employees of the food safety procedures within the food service establishment and teaching employees how to carry them out. Information may be presented in formats such as a set of instructions/illustrations, recipe cards with process instructions, wall charts, wallet cards, or live demonstration. The goal is to provide and document training for all food safety tasks in a format and frequency adequate to ensure employees have the knowledge to carry out the procedures consistently and effectively.

Monitoring (M): Routine observations and measurements conducted to determine if food safety procedures are being followed. Monitoring systems should include who, what, where, when, and how monitoring is to be performed and may be conducted visually or documented in writing. The goal is to move toward a well-documented system that can be verified and may include use of automated systems, digital thermometers, logs, charts, checklists, and other job aids and tools.

Background: CDC Risk Factors

- Food from Unsafe Sources
- Inadequate Cooking
- Improper Holding Temperatures
- Contaminated Equipment
- Poor Personal Hygiene.



Photo: <https://www.cdc.gov/foodsafety/keep-food-safe.html>

FSMS: The Past



FSMS & the Food Code

- FSMS & AMC: currently undefined terms in the FDA Model Code
- 8-201.11 When Plans Are Required.
 - Construction, conversion or remodeling
- 8-201.12 Contents of the Plans and Specifications
 - (A) Intended menu;
 - (B) Anticipated volume of FOOD to be stored, prepared, and sold or served;
 - (C) Proposed layout, mechanical schematics, construction materials, and finish schedules;
 - (D) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;
 - (E) Evidence that standard procedures that ensure compliance with the requirements of this Code are developed or are being developed; and
 - (F) Other information

FSMS & the Food Code

- 8-203.10 Preoperational Inspections.
 - The REGULATORY AUTHORITY shall conduct one or more preoperational inspections to verify that the FOOD ESTABLISHMENT is constructed and equipped in accordance with the APPROVED plans and APPROVED modifications of those plans, has established standard operating procedures as specified under ¶ 8-201.12(E), and is in compliance with LAW and this Code.
- 2-103.11 (Duties)Person in Charge. The PERSON IN CHARGE shall ensure:
 - (D) EMPLOYEES are effectively cleaning their hands, by routinely monitoring the EMPLOYEES' handwashing.
 - (G) EMPLOYEES are properly cooking TIME/TEMPERATURE CONTROL FOR SAFETY FOOD...
 - (H) EMPLOYEES are using proper methods to rapidly cool TCS food...
 - (L) EMPLOYEES are properly SANITIZING cleaned multiuse EQUIPMENT and UTENSILS...
 - (Q) Written procedures and plans, where specified by this Code and as developed by the FOOD ESTABLISHMENT, are maintained and implemented as required.

Food Code Annex

FDA Food Code 2022

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

Annex

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

[519 Active Managerial Control](#)

[2 Introduction to HACCP](#)

[3 The HACCP Principles](#)

[4 The Process Approach – A Practical Application of HACCP at Retail to Achieve Active Managerial Control](#)

[5 FDA Retail HACCP Manuals](#)

[6 Advantages of Using the Principles of HACCP](#)

[7 Summary](#)

[8 Acknowledgments](#)

[9 Resources and References](#)

1. Active Managerial Control

A. What is the common goal of operators and regulators of retail food and food service establishments and what is presently being done to achieve this goal?

The common goal of operators and regulators of retail and food service establishments is to produce safe, quality food for consumers. Since the onset of regulatory oversight of retail and food service operations, regulatory inspections have emphasized the recognition and correction of food safety violations that exist at the time of the inspection. Recurring violations have traditionally been handled through re-inspections or enforcement activities such as fines, suspension of permits, or closures. Operators of retail and food service establishments routinely respond to inspection findings by correcting violations, but often do not implement proactive systems of control to prevent violations from recurring. While this type of inspection and enforcement system has done a great deal to improve basic sanitation and to upgrade facilities in the United States, it emphasizes reactive rather than preventive measures to food safety. Additional measures must be taken on the

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FDA Food Code 2022

Annex 5. Conducting Risk-Based Inspections

Annex

5 Conducting Risk-Based Inspections

[1. Purpose and Scope](#)

[2. RISK-based Routine Inspections](#)

[3. What Is Needed to Properly Conduct a Risk-Based Inspection?](#)

[4. RISK-based Inspection Methodology](#)

[5. Achieving On-Site and Long-Term Compliance](#)

[6. Inspection Form and Scoring](#)

[7. Closing Conference](#)

[8. Summary](#)

1. Purpose and Scope

This Annex provides regulatory program managers and front-line inspection staff with guidance on planning, scheduling, conducting, and evaluating risk-based inspections. The FDA's *Voluntary National Retail Food Regulatory Program Standards* (Program Standards)

(<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm>) provide additional recommendations to assist regulatory program managers in the planning and development of a risk-based inspection program.

The primary focus of this Annex is to provide inspectors with methods for conducting risk-based inspections. Various strategies that can be used by regulatory professionals to assist operators in achieving active managerial control of foodborne illness risk factors are also included in this Annex.

As presented in Annex 4, the Centers for Disease Control and Prevention (CDC) Surveillance Report for 1993-1997, "Surveillance for Foodborne Disease Outbreaks – United States" (<http://www.cdc.gov/mmwr/preview/mmwrhtml/ss4901a1.htm>) identifies the most frequently reported contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the FDA as "foodborne illness risk factors."

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**Managing Food Safety:
A Regulator's Manual
For Applying HACCP
Principles to Risk-
based Retail and Food
Service Inspections
and Evaluating
Voluntary Food Safety
Management Systems**

Additional copies are available from:

*Office of Food Safety
Retail Food and Cooperative Programs
Coordination Staff/Retail Food Protection Team (HFS-320)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 240-402-2349*

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

[April 2006]

OMB Control No. 0910-0578
Expiration Date: 01/31/2013
See additional PRA statement in Annex 8 of this manual



**Managing Food
Safety:
A Manual for the
Voluntary Use of
HACCP Principles
for Operators of
Food Service and
Retail
Establishments**

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FDA OTED Courses

Risk-Based Inspection Methods at Retail

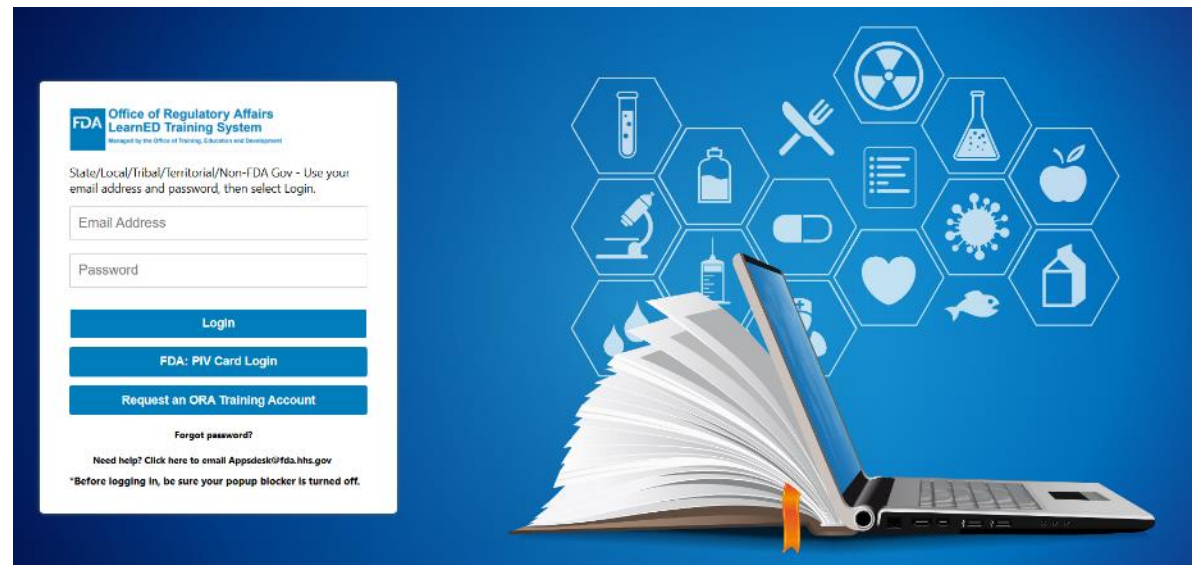
FD218 Student Manual

3rd Edition, Printing-Oct 2018



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2015-2016 Deli Data Collection Baseline to Assess Trends During 10-Year Study Period

Industry Segment	Facility Type	Initial Data Collection Period (Baseline Measurement)	2 ND Data Collection Period	3 RD Data Collection Period
Retail Food Store	Deli Department	Oct. 1, 2015 To Dec. 31, 2016	Oct. 1, 2019 To Dec. 31, 2020	Oct. 1, 2023 To Dec. 31, 2024

Foodborne Illness Risk Factors and the Associated Primary Data Items Examined in the Study

Foodborne Illness Risk Factor	Associated Primary Data Item Numbers and Description
Poor Personal Hygiene	<ul style="list-style-type: none"> • Data Item #1 – Employees practice proper handwashing. • Data Item #2 – Employees do not contact ready-to-eat foods with bare hands.
Contaminated Equipment/Protection from Contamination	<ul style="list-style-type: none"> • Data Item #3 – Food is protected from cross contamination during storage, preparation, and display. • Data Item #4 – Food contact surfaces are properly cleaned and sanitized.
Improper Holding Time/Temperature	<ul style="list-style-type: none"> • Data Item #5 – Foods requiring refrigeration are held at the proper temperature. • Data Item #6 – Foods displayed, or stored hot are held at the proper temperature. • Data Item #7 – Foods are cooled properly. • Data Item #8 – Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening.
Inadequate Cooking	<ul style="list-style-type: none"> • Data Item #9 – Raw animal foods are cooked to required temperatures. • Data Item #10 – Cooked foods are reheated to required temperatures.

Data Item Supported by Information Statements

				Data Item	
IN	OUT	NO	NA		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Raw animal foods are cooked to required temperatures	

				Information Statements	
IN	OUT	NO	NA		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw shell eggs broken for immediate service are cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Pork; Fish; Beef; Commercially-raised Game Animals are cooked to 145°F (63°C) for 15 seconds	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Comminuted Fish, Meats, Commercially-raised Game Animals are cooked to 155°F (68°C) for 15 seconds	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratite; or stuffing containing fish, meat, poultry, or ratites; wild game animals are cooked to 165°F (74°C) for 15 seconds	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specifies and according to oven parameters per Chart <i>(NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).</i>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Other Cooking Observations (describe in the Comment Section and Temperature Chart below)	

Elements of a Food Safety Management System

- **Procedures (P):** A defined set of actions for accomplishing a task in a way that minimizes food safety risks
- **Training (T):** The process of management's informing employees of the food safety procedures and teaching employees how to carry them out
- **Monitoring (M):** Routine observations and measurements conducted to determine if food safety procedures are being followed and maintained

FSMS Score Description

- 1 Nonexistent:** No system in place or system haphazardly implemented (no defined structure or frequency for implementation)
- 2 Underdeveloped:** System is in early development. Efforts are being made, but there are crucial gaps in completeness and/or consistency
- 3 Well-developed:** System is complete, consistent, and oral or a combination of oral and written. The preponderance of the management system is oral
- 4 Well-developed and Documented:** System is complete, consistent, and primarily written. The preponderance of the management system is written

Calculating Food Safety Management System Scores

EXAMPLE – Poor Personal Hygiene Risk Factor

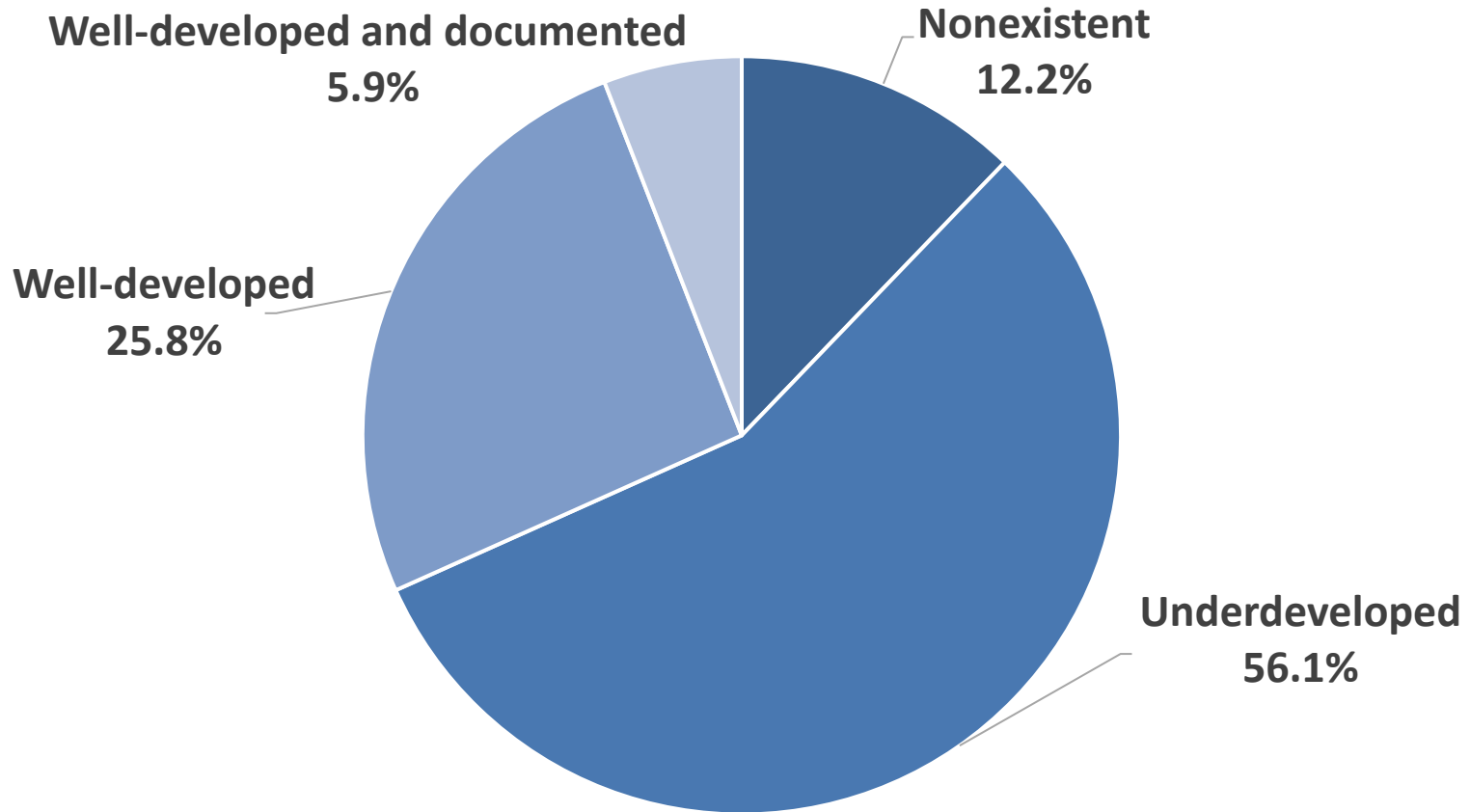
Data Item	Procedures	Training	Monitoring
#1 – Employees practice proper handwashing	2	3	3
#2 – Employees do not contact ready-to-eat foods with bare hands	2	2	3

The score is calculated as the sum of all the PTM ratings divided by the number of ratings given:

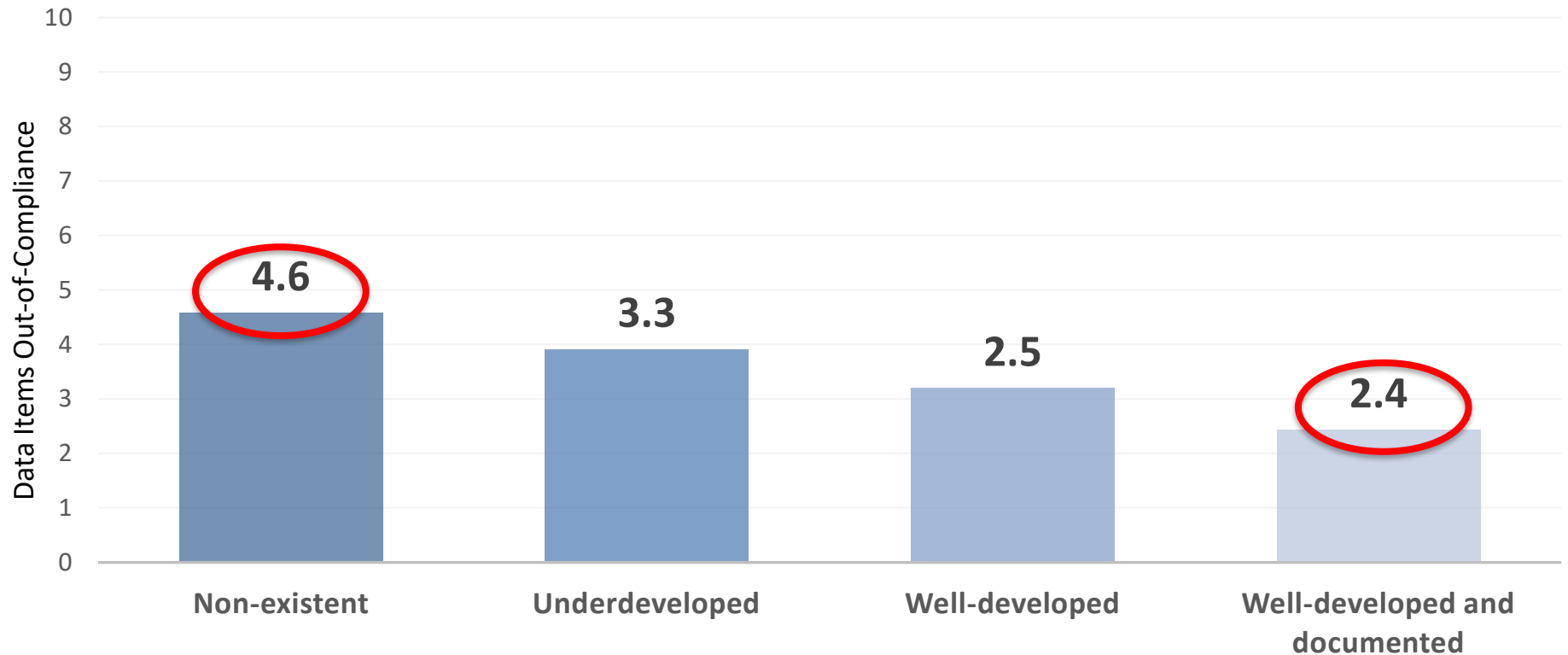
$$2+3+3+2+2+3 = 15/6 = \underline{\underline{2.5}}$$

FSMS Description	FSMS Calculated Score
Non-Existent	1.0
Underdeveloped	>1.0 and <3.0
Well Developed	≥3.0 and <4.0
Well Developed & Documented	4.0

Food Safety Management System Results



Average Number Primary Data Items Out-of-Compliance by Food Safety Management System Category



Key Takeaways

- Best control over
 - No bare-hand contact with Ready-to-eat (RTE)
 - Raw animal foods cooked to required temps
- Need better control
 - Employee handwashing
 - Cold holding
 - Cooling foods properly
- Food Safety Management Systems (FSMS) strongest predictor of items being out of compliance
- Certified Food Protection Manager (CFPM) enhances FSMS



Issue 2020 II-030 Committee Charges

The Conference recommends a Food Safety Management System (FSMS) Committee be created and work with stakeholders such as but not limited to the Retail Food Safety Regulatory Association Collaborative to identify recommendations for developing and implementing documented, HACCP principles-based Food Safety Management Systems (FSMSs) in all food establishments to support FDA's blueprint for a New Era of Smarter Food Safety. The FSMS Committee should consider:

1. Identifying barriers to the universal *voluntary* development and implementation of documented FSMSs consistent with Annex 4 of the Food Code.
2. Identifying solutions for overcoming the identified barriers in #1 and provide recommendations for how to promote the solutions.
3. Conducting a pros/cons assessment of including a requirement for the development and implementation of documented FSMSs, consistent with Annex 4, in a future edition of the Food Code. In the assessment, the committee should consider providing feedback on:
 - a) the hurdles/challenges involved in such a requirement; and
 - b) recommendations on how a requirement might best be incorporated to proactively control foodborne illness risk factor occurrence while recognizing the diversity within the retail and food service industries. The committee should also consider a gap analysis of § 2-103.11 as a starting point.
4. Developing recommendations on next steps to promote universal development and implementation of documented FSMSs consistent with Annex 4.
5. The committee should report its findings and recommendations at the next Biennial Meeting of the Conference for Food Protection. While FDA's efforts will be ongoing during this time, the findings and recommendations will continue to be useful to the agency as it continues to implement its blueprint on retail modernization.

FSMS: The Present





2023 CFP: FSMS Committee Report

125 Barriers Identified

Economic Barriers

- Resource Barriers
- Equipment Barriers
- Time Barriers
- Cost Barriers

People Barriers

- Buy-in Barriers
- Leadership/Accountability Barriers
- Values Barriers
- Cultural/Ethnicity Barriers

Training Barriers

- Training Barriers
- Knowledge Barriers
- Processes Barriers
- System Development/SOPs Barriers
- Code Differences Barriers
- Resource Barriers
- Equipment Barriers
- Time Barriers
- Cost Barriers

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Solutions

135 solutions
were identified by
the committee

Economic Solutions

- Lack of resources
- Perception that implementing a FSMS is costly and difficult.
- Facilities are not designed to support FSMSs.
- Difficult to quantify the return on investment

People Solutions

- Buy-in Solutions
- Leadership/Accountability Solutions
- Values Solutions
- Cultural/Ethnicity Barrier Solutions

Training Solutions

- Training Solutions
- Knowledge Solutions
- Process Solutions
- System Development/SOP Solutions



Issue: 2023 II-043

Council
Recommendation: Accepted as Submitted _____ Accepted as Amended _____ X No Action _____

- **Title:** FSMS #2 Amend Food Code – Define Active Managerial Control and FSMS

that a letter be sent to the FDA requesting that the most current edition of the Food Code be amended as follows:

1. Section 2-103.11 Person in Charge be amended as follows (language to be removed is marked with strikethrough and language added is marked with underline format):

2-103.11 Person in Charge. The PERSON IN CHARGE shall ~~ensure that~~ perform ACTIVE MANAGERIAL CONTROL by:



Conference for Food Protection
2023 Issue Form



Issue: 2023 II-043

Council Recommendation: Accepted as Submitted _____ Accepted as Amended X No Action _____

2. Section 8-201.12 Contents of the Plans and Specifications. (E) Evidence that ~~standard procedures~~ a FOOD SAFETY MANAGEMENT SYSTEM ensures compliance with the requirements of this Code is developed or is being developed; and

3. Add definition of AMC to Chapter 1

4. Add FSMS definition to Chapter 1



Council
Recommendation: Accepted as Submitted _____ Accepted as Amended X No Action _____

Title: FSMS #3 Re-create FSMS Committee

Recommended Solution: The Conference recommends...:

The Food Safety Management System (FSMS) Committee be reestablished with the following charges:

1. Collaborate with the Retail Food Safety Regulatory Association Collaborative to create resources for establishments to develop a FSMS.
 2. Review 2021-2023 FSMS Committee Charges Report and identify specific items to develop remedies.
 3. Develop recommendations on next steps to promote universal development/implementation of a **documented FSMS to be included in a future edition of the Food Code.**
 4. Collaborate with the Retail Food Safety Regulatory Association Collaborative to conduct a cost/benefit analysis of an implemented FSMS.
 5. Report the committee's findings.
- Issue 2023 II-045 created the FSMS committee as a standing Committee

Council	Accepted as	Accepted as		
Recommendation:	Submitted	Amended	<u>X</u>	No Action

Title: PSC15 Incorporation of Plan Review into VNRFRPS Standard 3

- **Recommended Solution: The Conference recommends....:**
- incorporating plan review into Standard 3 - Inspection Program based on HACCP Principles.
 - 1.Add a new element seven (7) to Standard 3 - Inspection Program based on HACCP Principles to include:
 - (7) The jurisdiction develops and implements a program policy for conducting reviews of plans submitted by food establishments. The policy should include a **review and determination of the adequacy of facilities, equipment, and procedures** based on the establishment's intended menu, volume of food, flow of food, and food processes.



FSMS: The Future

Food Code Predictions

Present

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:

- (A) Intended menu;
- (B) Anticipated volume of FOOD to be stored, prepared, and sold or served;
- (C) Proposed layout, mechanical schematics, construction materials, and finish schedules;
- (D) Proposed EQUIPMENT types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;
- (E) Evidence that standard procedures that ensure compliance with the requirements of this Code are developed or are being developed; and
- (F) Other information that may be required by the REGULATORY AUTHORITY for the proper review of the proposed construction, conversion or modification, and procedures for operating a FOOD ESTABLISHMENT.

Future



- Evidence that a documented FOOD SAFETY MANAGEMENT SYSTEM to control risk factors is developed or is being developed.

Food Code Predictions

Present

8-203 Construction Inspection and Approval

8-203.10 Preoperational Inspections.

The REGULATORY AUTHORITY shall conduct one or more preoperational inspections to verify that the FOOD ESTABLISHMENT is constructed and equipped in accordance with the APPROVED plans and APPROVED modifications of those plans, has established standard operating procedures as specified under ¶ 8-201.12(E), and is in compliance with LAW and this Code.

Future



-has established and implemented a FOOD SAFETY MANAGEMENT SYSTEM as specified under 8-201.12(E)...

Food Code Predictions

Present

- **8-304.11 Responsibilities of the Permit Holder.**
 - Upon acceptance of the PERMIT issued by the REGULATORY AUTHORITY, the PERMITHOLDER in order to retain the PERMIT shall: (A-K)

Future



- (L) Ensure the FOOD SAFETY MANAGEMENT SYSTEM required under 8-201.12 is updated any time there are changes to the menu, equipment or procedures to address all risk factors as they relate to the food establishment.

Food Code Predictions

Present

2-103 Duties

2-103.11 Person in Charge.

The PERSON IN CHARGE shall ensure that: (A – Q)

Future



- The PERSON IN CHARGE shall ensure ACTIVE MANAGERIAL CONTROL by:
 - Implementing the FOOD SAFETY MANAGEMENT SYSTEM required under 8-201.12.

Impact on RA Activities

- Additional Resources
 - Plan review: focus/time on FSMS.
 - Pre-op inspections: construction & FSMS evaluation.
 - Inspections: Eval. of Code compliance & FSMS.
 - Compliance & enforcement.
- Additional Benefits
 - Decrease in inspections/re-inspections over time.
 - Decrease in FBI Risk Factors (fewer illness/outbreaks, decrease in outbreak investigations)
 - Decrease in compliance & enforcement actions.
 - Better public health protection

Impact on Industry

- Additional Resources
 - FSMS plan development (procedures)
 - Training
 - Monitoring
 - Recordkeeping
- Additional Benefits
 - Decrease in FBI Risk Factors (illnesses/outbreaks)
 - Decrease in inspection frequency
 - Aid in training new employees
 - Help establish food safety culture



Additional Resources for Regulatory & Industry

FDA

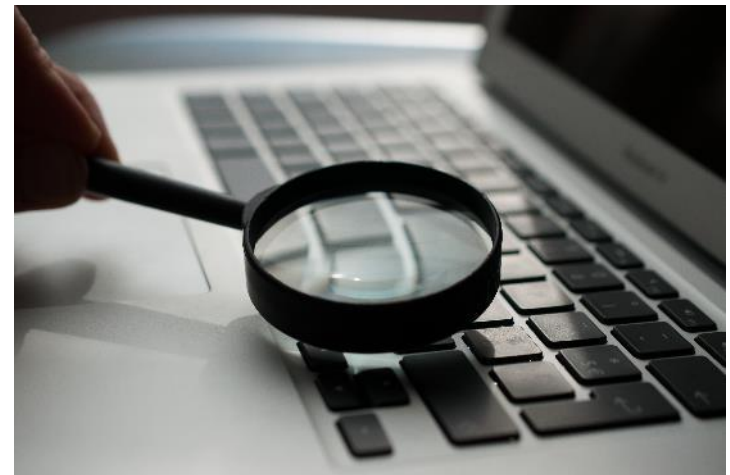
- CFP
- Association Partners: NEHA, AFDO, NACCHO, ASTHO & Affiliates.
- Federal Partners: FDA, USDA, CDC.
- Retail Food Safety Regulatory Association Collaborative.
- State, Local, Tribal & Territorial Partners
- Industry Leaders & Associations



Retail Food Safety Regulatory
Association Collaborative

Technology & FSMS

- Hardware, software, data storage is accessible & relatively inexpensive.
- Can assist with PTM.
- Automated alarms & notifications.
 - CL deviations.
 - Monitoring/task reminders.
- Data is easily reviewed & shared.
 - Management review
 - RA review????
- CFP DFSMS Report - General Best Practice Guidelines for Digital Food Safety Management
 - Recommendations for the design of DFSMS and equipment



Thank You!

Questions?

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