

Factsheet: The Occurrence of Foodborne Illness Risk Factors in Retail Food Store Delis 2015-2016

The 2013-2024 FDA Retail Food Risk Factor Study examines the occurrence of foodborne illness risk factors, food safety practices, and behaviors in retail food establishments. In the 2015-2016 Retail Food Store Deli Data Collection study, the agency investigated the relationship between food safety management systems (FSMS), certified food protection managers (CFPM), and the occurrence of risk factors and food safety behaviors and practices commonly associated with foodborne illness in retail food store delis from 2015 to 2016. Data from this study will provide valuable insights that FDA can use to develop educational resources and guidance to improve food safety practices.

Food safety management systems (FSMS) play a major role in compliance

Inadequate FSMS were the strongest predictor of data items being out-of-compliance in retail food store delis. As shown in the table, the average number of out of compliance items is greatly reduced when there is a well-developed FSMS.

Delis with well-developed FSMS had almost half as many risk factors and food safety practices that were out of compliance than delis with non-existent FSMS.

Retail Food Store Deli	Non-existent FSMS	Well-developed FSMS
Average # of out of compliance items	4.6	2.4



Impact of a Certified Food Protection Manager (CFPM)

Delis with a CFPM present had fewer primary data items out of compliance than those without a CFPM. Delis that had a CFPM who was the person in charge at the time of data collection had significantly better food safety management scores than those that did not have a CFPM present or employed.

Control over Foodborne Illness Risk Factors

Of the foodborne illness risk factors studied, delis had the best control over “inadequate cooking.” There remains a need to gain better control over “improper holding/time and temperature” and “poor personal hygiene.”

Two food safety behaviors/practices were identified as needing the most improvement:

- Cold holding of foods requiring refrigeration
 - ◊ Time/temperature control for safety (TCS) foods should be held under refrigeration at or below 41°F (5°C) to limit the growth of pathogens that may be present on the food
- Employee handwashing (includes both when to wash and how to wash properly)
 - ◊ Knowing when and how to properly wash hands is critical in reducing the spread of pathogens from food employees' hands to food, food contact surfaces, and equipment

Delis were found to have the best control over two food safety behaviors/practices:

- Ensuring no bare hand contact with ready-to-eat foods
- Cooking raw animal-derived foods (meat, poultry, eggs) to their required temperatures

The results of the 2013-2024 study will be used to:

- Inform retail food safety initiatives, policies, industry partnerships and targeted intervention strategies focused on controlling foodborne illness risk factors
- Provide technical assistance to state, local, tribal, and territorial regulatory professionals

For More Information

For more information regarding the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Retail Food Store Delis*, please visit: <http://www.fda.gov/retailfoodriskfactorstudy>.



Guidance Document For Unattended Food Establishments



**Prepared by the
Unattended Food Establishment Committee
2014-2016 Conference for Food Protection**

**Accepted by Assembly of State Delegates
April 2016**

**Revised by the
Unattended Food Establishment Committee
2016-2018 Conference for Food Protection**

**Accepted by Assembly of State Delegates
April 2018**

The guidance in this document does not create or confer any rights for or on any person and does not operate to bind public health officials or the public. An alternative approach may be utilized if the approach satisfies the requirements of the applicable statutes and regulations within a government's jurisdiction. Whether this guidance or an alternative procedure is utilized, contact the state or local public health authority responsible prior to implementation.

Table of Contents

Preface	3
Charge No. 1	3
Charge No. 2	3
Introduction	4
Minimum Requirements for an Unattended Food Establishment	4
A. Definitions	4
B. Plan Review	4
C. Location	4
D. Nature and Source of Food and Beverages	4
E. Refrigerated Display Equipment	5
F. Food Service Equipment Limitations	5
G. Food Protection	5
H. Unattended Food Establishment Oversight	6
I. Designation of Responsibilities	6

Preface

Council I of Conference for Food Protection (CFP) re-established the Unattended Food Establishment (UFE) Committee for 2016-2018 in response to Issue 2016-I-015. The committee was charged to:

- (A) Develop recommendations on how the FDA Food Code addresses Unattended Food Establishments;
- (B) Continue to review the "Guidance Document for Unattended Food Establishments" and any existing guidance from FDA and others to update the CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet sections 2-101.11 and 2-103.11 of the 2013 Food Code; and
- (C) Present their findings at the 2018 CFP Biennial Meeting.

History:

Council I of the Conference for Food Protection (CFP) formed the Unattended Food Establishment Committee, in response to Issue 2014-I-019, which was charged to:

- (A) Develop recommendations on whether and how the Food Code should be modified to address unattended food merchandising operations.
- (B) Consider any existing guidance from FDA and others and develop a CFP guidance document that could assist states when addressing the need to have alternative protective provisions in place when approving a waiver or variance for entities that do not meet sections 2-101.11 and 2-103.11 of the Food Code.
- (C) Report back to the 2016 Biennial Meeting with a recommendation to Council I.

The 2014-2016 UFE Committee Comments and Recommendations:

Upon completion of the guidance document, the Committee was unsure as to where to place the proposed requirements for an unattended food establishment in the Food Code. The proposed requirements cover a number of different sections of the Food Code and some requirements, such as video surveillance, have never been addressed in the Food Code.

The CFP Unattended Food Establishment Committee recommends that this information be placed on the CFP website for use as a guidance document. This document is intended to assist regulatory authorities and the foodservice industry in the review, approval and operation of unattended food establishments.

Introduction

A recent innovation in retail operations is the “unmanned food establishment”. This type of operation is typically located in office buildings or restricted break areas where access by the general public is somewhat restricted. While a wide variety of food items may be provided, these operations frequently offer packaged time/temperature control for safety food (TCS) and non-TCS food products that are displayed via refrigeration units, food racks, baskets and/or countertop display units. “Unmanned food establishments” may also be equipped with microwave ovens or offer automatically dispensed hot and cold beverages. The one common characteristic of these operations is that they lack the presence of an onsite person-in-charge (PIC).

As these operations have been observed, various jurisdictions have identified them by a variety of names including, but not limited to, micro-markets, self-service food markets and self-service retail convenience stores. Since this type of establishment is not specifically addressed in the FDA 2013 Food Code, impacted jurisdictions have found it necessary to individually address licensing requirements. Except where otherwise indicated in the document, the requirements of the Food Code for food establishments shall apply. For purposes of this guidance document below, such operations will be referred to as Unattended Food Establishments.

The 2014 Conference for Food Protection Biennial Meeting established the “Unattended Food Establishment Committee” which was tasked to develop a CFP guidance document that could assist state and local agencies in their regulation of these new entities. The committee proposes the following requirements need to be in place to allow the operation of an unattended food establishment:

Minimum Requirements for an Unattended Food Establishment

A) Definitions

- (1) Unattended Food Establishment means an operation that provides packaged foods using an automated payment system; and has controlled entry not accessible by the general public.
- (2) Controlled Entry means selective restriction or limitation of access to a place or location.

B) The plan review and food safety operating permit shall be in accordance with the requirements of the regulatory authority having jurisdiction.

C) Unattended Food Establishment Location

The unattended food establishment shall be located in the interior of a building that is not accessible by the general public. Access to the unattended food establishment shall be limited to a defined population (e.g., employees or occupants of the building where the establishment is located).

D) Nature and Source of Food and Beverages Offered for Sale

- (1) Only commercially packaged foods properly labeled for individual retail sale (per Food Code definition of packaged and labeled per ¶ 3-201.11(C)) are offered.

- (2) No unpackaged food is permitted except as provided by Subparagraph 3-302.11(B)(1) of the Food Code.
 - (3) Food preparation by consumers is limited to heating/reheating food in a microwave oven.
 - (4) No dispensing of bulk food is permitted. Bulk food is referred to as food that is dispensed to the customer without being commercially packaged for individual service or sale.
- E) Refrigerated Display Equipment
- (1) An unattended food establishment shall be equipped with refrigeration or freezer units that have the following features:
 - (a) Self-closing doors that allow food to be viewed without opening the door to the refrigerated cooler or freezer; and
 - (b) Automatic self-locking mechanism that prevents the consumer from accessing the food upon the occurrence of any condition that results in the failure of the refrigeration unit to maintain the internal product temperature specified under Food Code Subparagraph 3-501.16(A)(2) or freezer unit to maintain the product frozen.
- F) Food Service Equipment Limitations
- (1) Beverage Dispensing Equipment
 - (a) Beverage dispensers are limited to equipment that dispenses individual servings, such as those that dispense one cup of coffee at a time. (The use of any other beverage dispensing equipment may be permitted by the regulatory authority based upon the capability of the permit holder to properly clean and sanitize the equipment on the required frequency.)
 - (b) Beverage dispensers connected to the building water supply shall be properly equipped with backflow prevention per § 5-203.14 of the Food Code.
 - (2) Food Contact Surfaces
 - (a) Multi-use food-contact surfaces shall be cleaned on the frequency consistent with § 4-602.11 of the Food Code, or shall be easily removable and replaced with cleaned surfaces that have been transported in a sanitary manner.
 - (b) Multi-use food-contact surfaces intended for direct contact with TCS foods are not permitted.
- G) Food Protection
- (1) Security
 - (a) An unattended food establishment shall provide continuous video surveillance of areas where consumers view, select, handle and purchase products that provides sufficient resolution to identify situations that may compromise food safety or food defense.
 - i Video surveillance recordings shall be maintained and made available for inspection upon request by a representative of a regulatory agency within 24 hours of a request.

- ii Video surveillance recordings shall be held by the establishment for a minimum of fourteen (14) days after the date of the surveillance.
- iii If required by local regulations, provide customer notification of video surveillance within the unattended food establishment.

(b) The permit holder shall take reasonable steps necessary to discourage individuals from returning food and/or beverages that have not been selected for purchase.

(2) Routine Service at an Unattended Food Establishment:

(a) The permit holder is responsible for routine service of the unattended food establishment on a scheduled basis and at a frequency acceptable to the regulatory authority. Service may include, but is not limited to the following:

- i Ensuring food is in sound condition and unadulterated by checking food supplies and equipment for signs of product damage and/or tampering and the presence of recalled foods.
- ii Verifying refrigeration equipment is operating properly including the temperature display and self-locking mechanism.
- iii Cleaning food service equipment and food display areas.
- iv Stocking food and disposable single-use and single-service supplies.

(b) The permit holder shall assure:

- i Food is from an approved source.
- ii Packaged food is provided in tamper-evident packaging.
- iii Food is protected from potential sources of cross contamination.
- iv Food is maintained at safe temperatures during transport and display.

(H) Unattended Food Establishment Oversight

Each unattended food establishment shall have a sign readily visible at the automated payment station stating:

- (1) The name and mailing address of the business entity responsible for the establishment and to whom complaints and comments should be addressed.
- (2) The telephone number or other electronic contact information for the responsible business entity, when applicable.

(I) Designation of Responsibilities:

The permit holder bears all responsibilities for the operation of the food establishment. Where the permit holder is not the owner or operator of the building where the food establishment is located, a mutual agreement that outlines the responsibilities for cleaning and maintenance of all surfaces and equipment, provision of supportive facilities/services such as janitorial and restroom facilities, pest control and removal of solid waste may be approved by the regulatory authority. This agreement should also outline what actions must be taken by both parties to maintain the establishment in compliance with all requirements.

**Conference for Food Protection
2023 Issue Form**

Issue: 2023 II-039

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

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

FDC Issue 2–Amend 2022 FDA Food Code to add food defense rule under 2-102

Issue you would like the Conference to consider:

The committee voted YES, it is appropriate and recommends an additional knowledge area under 2-102.11(C) relating to Food Defense in food establishments. The committee also voted to propose two additional recommendations as appropriate:

ADD - 2-102.11 (C) (18) Explaining steps that are taken to prevent intentional ADULTERATION by CONSUMERS, FOOD EMPLOYEES, or other persons including monitoring operations, ingredients, supplies, and finished products for unusual or suspicious activities, and similar FOOD DEFENSE activities.

The committee also voted to propose these two additional recommendations as appropriate:

ADD - FOOD DEFENSE Definition:

1-201.10 "FOOD DEFENSE" is the effort to protect food from acts of intentional ADULTERATION.

ADD - 2-103.11 (Q) 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.

Public Health Significance:

Food establishment personnel play a key role in protecting food from someone intent on adulterating or tampering with the food to either cause illness or death on a large scale. These proposed updates to the 2022 FDA model Food Code describe steps that managers and persons in charge should take to promote employee awareness and report any suspicion of food adulteration or product tampering. It is not intended to require that all food employees attend a formal training or pass a test that is part of an accredited program.

In addition, Food Defense is not adequately defined or addressed in the 2022 FDA Model Food Code. Food Defense is an important topic because there have been several

intentional adulteration events related to food establishments in the United States and other countries. Examples include:

- 1984 Rajneeshee attack on 10 salad bars in Oregon (750 illnesses)
- 2002-2003 Nicotine poisoning of retail meats in Michigan (100 illnesses)
- 2009 Pesticide poisonings of salsa at a restaurant in Kansas (40 illnesses)
- 2016 Intentional contamination of RTE food at local grocery stores in Michigan (No illnesses)
- 2017 Intentional contamination of RTE food at restaurants in South Lake Tahoe in California (4 illnesses)
- 2018 Intentional tampering and contamination of food at multiple retail stores in Arizona (No illnesses)
- 2021 Intentional contamination of processed meat and microwaveable products at local stores in London (No illnesses)

Recommended Solution: The Conference recommends...:

A letter be sent to the FDA requesting that the most current edition of the Food Code be amended as follows (new language is underlined):

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, and similar food defense activities.

2-103.11 (Q) 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.

1-201.10 (B) "Food Defense" is the effort to protect food from acts of intentional adulteration.

Submitter Information 1:

Name: Albert Espinoza, R.S.
Organization: H-E-B
Address: 646 S. Flores
City/State/Zip: San Antonio, TX 78204
Telephone: 2108845783
E-mail: Espinoza.albert@HEB.com

Submitter Information 2:

Name: Jennifer M Bonsky
Organization: Michigan Department of Agriculture and Rural Development
Address: P.O. Box 30017
City/State/Zip: Lansing, MI 48933
Telephone: 15176140149
E-mail: bonskyj@michigan.gov

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Factsheet: The Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-Service Restaurants 2017-2018

The 2013-2024 FDA Retail Food Risk Factor Study examines the occurrence of foodborne illness risk factors, food safety practices, and behaviors in retail food establishments. In the 2017- 2018 Restaurant Data Collection study, the agency investigated the relationship between food safety management systems (FSMS), certified food protection managers (CFPM), and the occurrence of risk factors and food safety behaviors and practices commonly associated with foodborne illness in restaurants from 2017 to 2018. Data from this study will provide valuable insights that FDA can use to develop educational resources and guidance to improve food safety practices.

Food Safety Management Systems Play a Major Role in Compliance

Inadequate FSMS were the strongest predictor of data items being out-of-compliance in both fast food and full-service restaurants. As shown in the tables, the average number of out of compliance items is greatly reduced when there is a well-developed FSMS. This is true for both fast food restaurants and full-service restaurants.

Restaurants with well-developed FSMS had less than half as many risk factors and food safety practices that were out of compliance than restaurants with non-existent FSMS.



Fast Food Restaurants	Non-existent FSMS	Well-developed FSMS	Full-Service Restaurants	Non-existent FSMS	Well-developed FSMS
Average # of out of compliance items	4.5	1.5	Average # of out of compliance items	5.3	2.2

Impact of a Certified Food Protection Manager

Restaurants with a CFPM present had fewer primary data items out of compliance than those without a CFPM. Restaurants that had a CFPM who was the person in charge at the time of data collection had significantly better food safety management scores than those that did not have a CFPM present or employed.

Control Over Foodborne Illness Risk Factors

Of the foodborne illness risk factors, restaurants had the best control over inadequate cooking. There remains a need to gain better control over improper holding/time and temperature and poor personal hygiene.

Restaurants were found to have the best control over two food safety behaviors/practices:

- Ensuring no bare hand contact with ready-to-eat foods
- Cooking raw animal-derived foods (meat, poultry, eggs) to their required temperatures

Three food safety behaviors/practices were identified as needing the most improvement:

- Cold holding of foods requiring refrigeration:
Time/temperature control for safety (TCS) foods should be held under refrigeration at or below 41°F (5°C) to limit the growth of pathogens that may be present on the food
- Employee Handwashing (includes both when to wash and how to wash properly):
Knowing when and how to properly wash hands is critical in reducing the spread of pathogens from food employees' hands to food, food contact surfaces, and equipment
- Foods are cooled properly:
Excessive time for cooling TCS Food has been consistently identified as one of the leading contributing factors to foodborne illness.

The results of the 2013-2024 study will be used to:

- Inform retail food safety initiatives, policies, industry partnerships and targeted intervention strategies focused on controlling foodborne illness risk factors
- Provide technical assistance to state, local, tribal, and territorial regulatory professionals

For More Information

For more information regarding the *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-Service Restaurants*, please visit: <https://www.fda.gov/retailfoodriskfactorstudy>.

Significant Changes Chapter 2

- **2-101.11 (C) Assignment - Unattended Food Establishment**

The requirement to have a Person in Charge (PIC) present at the facility during all hours of operation does not apply to certain types of FOOD ESTABLISHMENTS deemed by the DEPARTMENT to pose minimal risk of causing, or contributing to, foodborne illness based on the nature of the operation and extent of the FOOD preparation.

ODA will use the **CFP Unattended Food Establishment guidance** document to establish criteria for low-risk facilities exempt from the PIC requirement.

- **2-102.11(C) Food Defense**

(CFP Issue 2023 II-039) The person in charge will be required to demonstrate an additional area of knowledge related to Food Defense in a food establishment.

- **2-102.12 Certified Food Protection Manager (CFPM)**

One CFPM will be required per facility **(requirement from the 2013 FDA Model code)**. ODA will develop criteria for facilities that will not require a CFPM. Additionally, ODA will develop a timeline for non-exempt facilities to obtain a CFPM. According to **data collected by the Oregon Health Authority**, the average cost is \$116 for the class and test and \$28 for the test only. Multiple national **FDA Retail Food Risk Factors Studies** have demonstrated that facilities with a CFPM showed a positive correlation between having a CFPM and improved control of risk factors related to foodborne illnesses.

2022 FDA Model Food Code Annex 3 Public Health Reason - *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.

- **2-103.11 Person in Charge**

Includes the following additional requirements of the PIC:

- Manager must ensure that employees maintain proper temperature control of TCS foods during thawing, hot holding, and cold holding.
- All required written plans and procedures are maintained and implemented.
- 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.

- **2-201.12 Exclusions and Restrictions**

Big 6 - Added Salmonella (non-typhoidal) to the list of excludable diseases for food employees.

- **2-201.13 Removal of Exclusions and Restrictions**

Food employee with diagnosed or presumptive Norovirus may return to work after vomiting and diarrhea have resolved for 48 hours.

- **2-301.16 Hand Antiseptics**

Provides additional requirements for hand antiseptics.

2022 FDA Model Food Code Public Health Reasons - *The provisions of § 2-301.16 are intended to ensure that an antimicrobial product applied to the hands is 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. Because of the need to protect workers and to ensure safe food, hand antiseptics must comply with both the human drug and the food safety provisions of the law.*

- **2-401.13 Use of Bandages, Finger Cots, or Finger Stalls**

If used, an impermeable cover such as a bandage, finger cot or finger stall located on the wrist, hand or finger of a FOOD EMPLOYEE working with exposed FOOD shall be covered with a single-use glove.

- **2-501.11 Clean up Vomiting and Diarrheal Events**

ODA will be requiring a written plan for the clean-up of vomiting and diarrheal events. There are numerous templates that have been developed by other jurisdictions that ODA may modify and provide to industry.

FDA Food Code Annex 3 Public Health Reason- Food establishment must have written procedures for employees to follow when responding to a vomiting or diarrheal event. 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.

ANSI-Accredited Classes

	Exam Only	Exam and Course
The Always Food Safe Company	\$28.00	\$78.00
Responsible Training	\$64.99	\$84.99
Relish Works Inc (DBA: Trust20)		\$90.00
AAA Trainers LLC	\$69.95	\$99.95
APS Culinary Dynamics (DBA: World Food Safety Organization)	\$95.00	\$117.00
U Serve	\$89.99	\$119.99
DSBWorldWide, Inc (DBA: EduClasses®)	\$65.00	\$120.00
Learn2Serve	\$69.99	\$121.00
State Food Safety	\$48.00	\$134.00
My Food Service License	\$99.00	\$139.00
National Restaurants Association Solutions (ServSafe)	\$99.00	\$179.00
Average	\$72.89	\$116.63