FDA U.S. FOOD & DRUG ADMINISTRATION

NATIONAL RETAIL FOOD TEAM

TECHNICAL REPORT: FDA REPORT ON THE OCCURRENCE OF FOODBORNE ILLNESS RISK FACTORS IN FAST-FOOD AND FULL-SERVICE RESTAURANTS

2017-2018

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State, local, and tribal regulatory jurisdiction representatives who accompanied FDA Retail Food Specialists on data collection visits.

INDUSTRY

Retail Food Store Managers of the establishments selected for the study for their cooperation and assistance during the data collections.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMS/ABBREVIATIONS

The following table describes the acronyms and abbreviations used throughout this report.

Acronym	Meaning
AMC	Active Managerial Control
ANOVA	Analysis of variance
ANSI	American National Standards Institute
CDC	Centers for Disease Control and Prevention
CFPM	Certified Food Protection Manager
CFSAN	Center for Food Safety and Applied Nutrition
ESRI	Environmental Systems Research Institute
FDA	U.S. Food and Drug Administration
FSMS	Food Safety Management Systems
HACCP	Hazard Analysis and Critical Control Points
TCS	Time/Temperature Control for Safety Food
PIC	Person in Charge
PTM	Procedures, Training, and Monitoring
RTE	Ready-to-Eat
PS	Voluntary National Retail Food Regulatory Program Standards

ABSTRACT

This report includes the background, design, and results of data collection on the occurrence of foodborne illness risk factors in the United States in fast-food and full-service restaurants from 2017-2018. It is the second of three data collection periods for this retail sector that are part of the U.S. Food and Drug Administration's (FDA) current 10-year study on trends in the occurrence of foodborne illness risk factors and food safety behaviors/practices in food service facilities. Data from the 2017-2018 collection will be used to assess trends in the occurrence of risk factors in future data collections. Of the foodborne illness risk factors investigated in this study, inadequate cooking was best controlled. The two most commonly occurring out-of-compliance risk factors were improper holding time/temperature and poor personal hygiene.

Establishments with well-developed FSMS had significantly fewer out-of-compliance food safety behaviors/practices than did those with "less developed" (underdeveloped and non-existent) FSMS. Neither the presence of a Certified Food Protection Manager (CFPM) nor the multiple-unit status of establishments were significant predictors of having out-of-compliance data items when all factors studied were taken into account. These findings suggest that well-developed and documented FSMS are a useful tool in reducing the occurrence of foodborne illness risk factors.

BACKGROUND

Foodborne illness remains a major public health concern in the United States. Foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths each year (Scallan et al., 2011). The annual economic burden from health losses due to foodborne illness is estimated at 90.2 billion dollars (Scharff, 2018).

The restaurant industry is a major driver of food service and food safety in the United States. Consumer demand for food away from home has led to increased spending in both fast-food and full-service restaurants (Powell et al., 2012; Stewart et al., 2004). This sector also employs approximately 14 million people (BLS, 2017). Along with this high demand comes the need for careful attention to food safety practices and behaviors that minimize the incidence of foodborne illness in these locations.

According to the Centers for Disease Control and Prevention (CDC) more than half of foodborne illness outbreaks that occur each year are associated with food from restaurants. When considering incidents in 2017 involving a single location of food preparation, for example, restaurants accounted for 489 outbreaks (64%) and 5,533 illnesses (44%) (CDC, 2017).

Foodborne Illness Risk Factors

Surveillance data from the CDC consistently identified five major risk factors related to food safety practices within the retail food industry that contribute to foodborne illness. Most regulatory retail food inspection programs throughout the United States monitor these risk factors in their routine inspections, and each necessitates specific food safety behaviors and practices to control the risks. These risk factors include:

- Poor personal hygiene
- Improper food holding/time and temperature
- Contaminated equipment/protection from contamination
- Inadequate cooking
- Food obtained from unsafe sources

Tracking the occurrence of foodborne illness risk factors provides a consistent means of monitoring food safety efforts and determining trends over time. Measuring and reporting on the occurrence of foodborne illness risk factors and food safety behaviors/practices at retail food establishments provide the foundation for identifying where risk-based interventions might have the greatest impact on enhancing public health protection. The FDA promotes and conducts research designed to inform the application of science-based food safety principles in retail and food service settings to minimize the incidence of foodborne illness. Research results support developing and delivering scientifically based guidance, training, program evaluation, and technical assistance to retail food regulatory agencies and the industries they regulate.

The FDA previously conducted a 10-year study between 1998 and 2008 to measure trends in the occurrence of foodborne illness risk factors and food safety behaviors/practices at retail. This study consisted of three data collection periods (1998, 2003, and 2008). The FDA summarized the findings for each data collection in separate reports (FDA, 2000; FDA, 2004; FDA, 2009). The FDA published a report in 2010 to summarize trends over the 10-year period and determined where progress had been made toward the goal of reducing the occurrence of risk factors in food service and retail food establishments (FDA, 2010).

At the conclusion of the 10-year study conducted between 1998 and 2008, the FDA determined that it needed to conduct additional research to identify the root causes associated with out-of-compliance risk factors and determine the most effective intervention strategies and inspection approaches for enhancing the safety of the nation's retail food protection system.

Purpose of the Study

The FDA is conducting a new 10-year study to investigate the relationship between FSMS, CFPM, and the occurrence of risk factors and food safety behaviors/practices commonly associated with foodborne illness at retail.

The objectives of this study are to:

- Identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in retail food establishments within the United States.
- Determine the extent to which FSMS and the presence of a CFPM impact the occurrence of foodborne illness risk factors and food safety behaviors/practices; and
- Determine whether the occurrence of foodborne illness risk factors and food safety behaviors/practices in retail food establishments differs based on an establishment's risk categorization and status as a single-unit or multiple-unit operation (e.g., restaurants that are part of an operation with two or more locations).

FSMS refers to a specific set of actions used by food service establishments to help achieve Active Managerial Control (AMC). 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. While the components of FSMS vary across the retail and food service industry, purposeful implementation of procedures, training, and monitoring are consistent components of FSMS. There are several systems and tools available internationally to achieve AMC. Some of the most notable systems include International Organization for Standardization (ISO 22000), Good Manufacturing Practices, Hazard Analysis and Critical Control Points, British Retail Consortium, and Safe Quality Food Institute (Codex, 2003; ISO 22000:2005, 2005; Luning et al., 2008). However, the ongoing prevalence and degree of implementation of these or similar systems within retail food stores in the United States remains understudied. Inadequate FSMS are thought to contribute to the worldwide burden of foodborne disease (Luning et al., 2008). For example, HACCP has been shown to have positive effects on food safety. However, without robust procedures, training, and monitoring, poor implementation can occur. This poor implementation has been described as a precursor to foodborne outbreaks (Cormier, 2007; Luning et al., 2009; Ropkins & Beck, 2000).

A CFPM is an individual who has shown proficiency in food safety information by passing a test that is part of an accredited program (FDA, 2013a). Research has shown that the presence of a CFPM is associated with improved food safety knowledge and inspection scores (Cates et al., 2008; Brown et al., 2014).

The results of this 10-year study period will be used to:

- Develop retail food safety initiatives, policies, and targeted intervention strategies focused on controlling foodborne illness risk factors
- Provide technical assistance to state, local, tribal, and territorial regulatory professionals
- Identify FDA retail work plan priorities
- Inform FDA resource allocation to enhance retail food safety nationwide

Restaurant Data Collection

This report describes the data collected in full-service and fast0-food restaurants in 2017-2018 data from this collection will be compared to baseline data collected in 2013 and used to assess trends in the occurrence of risk factors during a third data collection. Results for fast-food and full-service restaurants are presented together. When reviewing and analyzing the data, however, it is not appropriate to directly compare the results between fast-food and full-service restaurants. The differences in operational variables, complexities of menus, operations, and procedures between each restaurant type create distinct environments that do not lend themselves to direct comparison. Additional information can be found in Appendix D of this report.

Restaurants and Norovirus

Norovirus has been a pathogen of concern for the restaurant industry. Prevention strategies for norovirus are centered on preventing viral contamination and transmission, however there is currently no single effective strategy for preventing foodborne norovirus in food establishments. This is why the FDA Food Code recommends the use of a combination of prevention strategies, and why the development of FSMS to systematically reduce the risk of norovirus is so important. Norovirus is recognized globally as the most common cause of acute gastroenteritis in people of all ages and is responsible for the greatest burden of disease of all foodborne illnesses, resulting in over 200,000 deaths each year throughout the world (Pires, 2015; WHO, 2010).

In a study of restaurant-associated outbreaks in the United States from 1998-2013, Angelo, Nisler, Hall, Brown and Gould (2016) identified 9,788 restaurant-associated outbreaks. Of the total outbreaks associated with a single confirmed etiology, 3,072 (46%) were caused by Norovirus. Activities related to food handling and preparation practices were the most commonly reported contributing factors within restaurant-associated outbreaks. Food can be contaminated with Norovirus via contact with feces or contaminated water, vomit or water contaminated with vomit, aerosols generated by infected people, soiled materials, or soiled hands.

Infected symptomatic individuals shed large numbers of the virus in the vomit and stools primarily during the period of active symptoms, although both pre-symptomatic and post-symptomatic viral

shedding also occurs (Goller et al., 2004). Typical duration of viral shedding in adults lasts 20-30 days (Pringle, et al., 2015), with a brief period of increased infectiousness at onset of symptoms and a gradual decline in infectivity during asymptomatic transmission (Zelner, et al., 2013).

Preventing ill food employees from spreading pathogens to food and food contact surfaces remains an important objective of retail food safety policy in the United States. FDA's Food Code targets prevention of Norovirus by containing certain provisions that speak to responsibilities of the permit holder and food employees to report symptoms/diagnosis; managing ill employees by way of exclusion and restriction criteria (employee health policies); handwashing criteria (when and how to wash); responding to vomiting and diarrheal events; preventing contamination from employees (cleaning/sanitizing frequencies and no bare hand contact) and discarding of ready-to-eat (RTE) food that may have been contaminated by an employee who was restricted or excluded.

Prevention strategies are centered on preventing viral contamination and transmission. However, there is currently no effective single preventive strategy for preventing foodborne norovirus in food establishments. This is why the FDA Food Code recommends the use of a combination of prevention strategies.

FDA has vested interest in identifying strategies to significantly reduce Norovirus and illness from contaminated food in retail food establishments. FDA has conducted studies that will provide information needed to identify where increased emphasis or modifications to Norovirus mitigations could lead to significant reductions in norovirus transmission and illness from contaminated food in retail establishments

Intervention Strategies and Factors of Interest

Active Managerial Control

To help prevent foodborne illness, the FDA Food Code emphasizes the need for risk-based preventive controls and daily AMC of the risk factors contributing to foodborne illness in retail and food service facilities. A food establishment's success in achieving AMC involves the continuous identification and proactive prevention of food safety hazards. Two strategies supporting AMC efforts in food establishments that have received growing attention are the presence of CFPMs and FSMSs.

Regulatory Authority Characteristics

Regulatory authorities at local, state, territorial, and tribal levels have a number of unique organizational and regulatory requirements and implementation and disclosure practices. These factors vary across jurisdictions and can include, among others, enrollment in the Voluntary National Retail Food Regulatory Program Standards (PS) (FDA, 2015), implementation of grading systems (e.g., posting letter grades like A, B, and C), requirement for establishments to have a CFPM, and the

publication of inspection results (e.g., posting inspection reports online). Including this information as part of the data collection provides an opportunity to assess how elements within a regulatory retail food protection program may influence the relationship between FSMS, CFPM, and the occurrence of risk factors and food safety behaviors/practices.

Restaurant Characteristics

In addition to local jurisdictional requirements with which restaurants must comply, restaurants themselves differ in complexity of food preparation and organizational structure. For example, research has found that restaurants that are part of a multiple-unit operation (e.g., restaurant's part of an operation with two or more units) have fewer food safety violations per inspection as compared to single-unit operations (Leinwand et al., 2017). Including food preparation and organizational structure information for each restaurant in this data collection allows for assessing how the occurrence of food safety behaviors/practices in restaurants differs based on complexity of food preparation and status as a single-unit or multiple-unit operation.

DESIGN AND METHODOLOGY

Study Design

This study was conducted as an observational study of restaurants throughout the United States. Trained data collectors observed and recorded the food safety practices of retail food management and staff using a standardized data collection tool during normal business hours. More information on the study design can be found in Appendix C.

Restaurant Selection

In 2013, FDA obtained Office of Management and Budget (OMB Control #0910-0744) approval to initiate the first phase of the study, which focused on data collection within the restaurant segment of the industry. This approval was extended in 2016 to continue the study. In this study, the restaurant segment of the industry is sorted into two categories:

- Fast-food restaurants
- Full-service restaurants

For this study, fast-food and full-service restaurants are distinguished by how customers order and are served their meals. A description of restaurant facility types included in this study can be found in Table 1.

Table 1 Description of Restaurant Facility Types Included in the Study

Facility Type	Description
Full-service Restaurant	A restaurant where customers place their order at their table, are served their meal at their table, receive the service of the wait staff, and pay at the end of the meal.
Fast-Food Restaurant	A restaurant that is not a full-service restaurant. This includes restaurants commonly referred to as quick-service restaurants and fast-casual restaurants.

Restaurant Eligibility

This study was intended to examine food safety practices in restaurants that conduct a significant amount of on-site food preparation. Restaurants were randomly selected to participate in the study from among all eligible establishments located within a 150-mile radius from the home locations of the 22 FDA Retail Food Specialists performing the data collection. For this study, the complexity of food preparation was represented by the food establishment's risk categorization as found in Annex 5 of the 2013 FDA Food Code (see Table 2). This risk categorization was used to determine if an establishment was eligible for data collection. Restaurants that only served pre-packaged food or conducted low-risk food preparation activities, and restaurants that only operated seasonally were ineligible for selection. Establishments eligible for study selection fell into risk categories 2 through 4, as these food establishments represent more complex food preparation activities.

Table 2 Risk Categorization of Food Establishments

Risk Category	Description
1	Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged non-time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved AMC of foodborne illness risk factors.
2	Examples may include retail food store operations, schools not serving a highly susceptible population, and quick-service operations. Limited menu. Most products are prepared/cooked and served immediately. May involve hot and cold holding of TCS foods after preparation or cooking. Complex preparation of TCS foods requiring cooking, cooling, and reheating for hot holding is limited to only a few TCS foods. Establishments that would be otherwise grouped in Category 3 but have shown through historical documentation to achieve active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of AMC of foodborne illness risk factors is achieved and documented.

Risk Category	Description
3	An example is a full-service restaurant. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved AMC of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of AMC of foodborne illness risk factors is achieved and documented.
4	Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments that serve a highly susceptible population or that conduct specialized process, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.

Source: Annex 5, 2013 FDA *Food Code*.

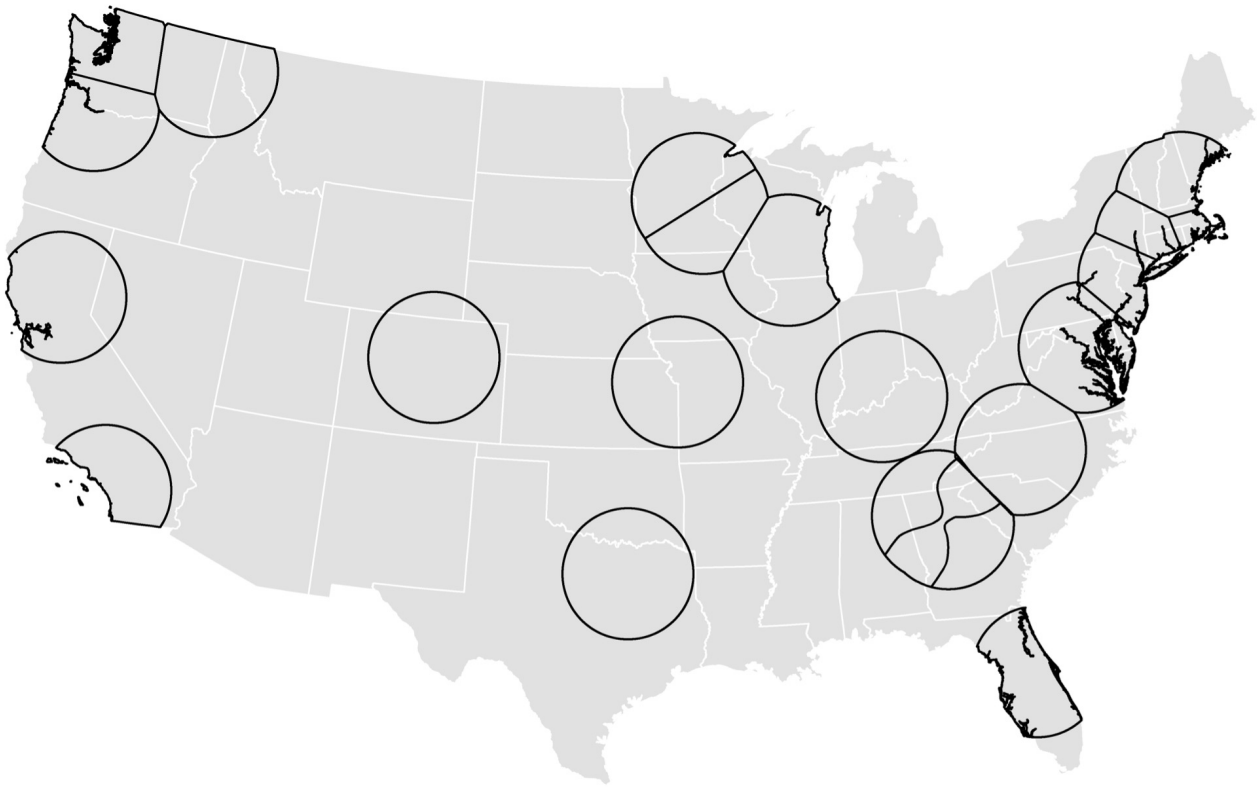
Data Collection

All data collection was conducted by Retail Food Specialists who have technical expertise in food safety and a solid understanding of food service operations within the restaurant industry. The data collectors conducted site visits throughout the United States at randomly selected restaurants to perform data collections. All data collectors received customized training specific to the study data collection protocol and marking instructions for the data collection tool. FDA's Center for Food Safety and Applied Nutrition (CFSAN) personnel standardized the data collectors in applying and interpreting the FDA Food Code utilizing the FDA Procedures for Standardization of Retail Food Safety Inspection Officers. In addition, all data collectors possessed technical expertise in retail food safety and a solid understanding of food service operations within the restaurant industry.

Restaurant Selection

A Geographic Information System database containing a listing of U.S. businesses was used to identify the inventory of restaurants for data collection. The total number of establishments in the country was approximately 636,473. Restaurants were randomly selected from among all eligible establishments located within a 150-mile radius of the home locations of the twenty-two data collectors. The number of establishments within the sampling zones was 408,465. As a result, roughly 64.2% of all establishments in the restaurant segment were eligible for selection. Figure 1 depicts the sample selection coverage area

Figure 1 Sample Selection Coverage Areas



Sample Size and Confidence Interval

The CFSAN Biostatistics Team determined that a minimum of 384 data collections of each restaurant facility type was needed during the initial and subsequent data collection periods. This sample size provides sufficient observations of food safety practices to be 95% confident that compliance percentages derived from the data collections are within 5% of their actual occurrence. For this study, the sample size was 430 data collections for full-service restaurants and 421 for fast-food restaurants.

Restaurants were randomly selected within the sampling zones. The sample establishment inventory was distributed evenly among the data collectors. Since industry participation in the study was voluntary, a list of substitute restaurants was selected for each data collector for establishments that were found to be misclassified, closed, or otherwise unable or unwilling to participate. The CFSAN Biostatistics Team randomly selected and maintained the inventory of substitute establishments.

Study Protocol and Methodology

Appendix A reproduces the data collection form used to collect observations in this study. A comprehensive presentation of the study protocol for data collection and marking instructions for the data collection form can be accessed using the web links provided in the References for the following documents:

- Food and Drug Administration (2013b), *Study on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2024– Protocol for the Data Collection*
- Food and Drug Administration (2013c), *Retail Food Program Foodborne Illness Risk Factor Study – Marking Instructions for the Data Collection Form*

Eligibility Verification of Randomly Selected Restaurants

The state or local jurisdictions with regulatory responsibility for conducting retail food inspections of the selected restaurants were contacted prior to conducting a data collection at the establishment. Data collectors verified, through discussions with the regulatory authority, whether the restaurant was under any legal notice. If the selected restaurant was under a legal notice, closed, or misclassified, the data collector did not conduct a data collection at that establishment, and a substitute was randomly selected.

Regulatory Authorities of Selected Restaurants

As part of the initial contact with the state or local regulatory authority, the data collector obtained information pertaining to its retail food inspection program, such as enrollment status in the PS, frequency of regulatory inspections, use of grading systems, posting of inspection results, manager certification requirements, and required food handler training. This information was included as part of the data collection for the selected restaurants to provide an opportunity to assess how elements within a regulatory retail food protection program impact the relationship between FSMS, CFPM, and the occurrence of risk factors and food safety behaviors/practices.

Each data collector extended an invitation to the state or local regulatory agency representative to accompany him or her during the data collection. When restaurant conditions merited regulatory actions, the accompanying state or local representative could intervene to ensure appropriate corrective actions were taken. If a state or local representative was not with the data collector during the data collection and conditions warranted regulatory action, the data collector contacted the regulatory authority after completing the data collection so that any necessary follow-up could occur.

Data Collection Protocol

The data collector conducted an unannounced, non-regulatory visit to each selected restaurant. Upon arrival at the establishment, the data collector explained the purpose of the visit to the owner or person in charge (PIC). An introductory letter explaining the purpose of the data collection visit, included in Appendix B, was also presented to the PIC. If the owner or PIC denied entry into restaurant, data collection was not performed, and a substitute restaurant was randomly selected to replace the one that opted not to participate in the study.

The data collector used the current version of the Food Code (FDA, 2013a) as the standard of measurement for compliance markings for observations of employee food safety behaviors/practices. Quantitative measurements of food product temperatures, sanitizer concentrations, and dish machine final rinse temperatures were collected using calibrated equipment such as thermocouples, heat-sensitive tape, and maximum registering stem thermometers. Visual observations of food safety practices were supplemented by asking questions of food employees and/or managers to ensure data collectors had a clear understanding of food processes and procedures. The owner or PIC of the restaurant was encouraged to accompany the data collector during the data collection.

Risk Factors and Associated Data Items

This study focused on observation and/or measurement of food safety practices/behaviors associated with the occurrence of foodborne illness risk factors. Four foodborne illness risk factors, comprising specific food safety behaviors, were used as the key indicators for FDA's statistical analysis for this study. Data items in this study were based on the FDA Food Code, which represents FDA's 15 best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service (FDA, 2013a). Table 3 presents the 10 data items and their associated risk factors. Although ensuring that food is obtained from an approved source is the first line of defense for restaurants, the current study design did not include this risk factor under the primary data items. This decision was made because the agency observed low out-ofcompliance percentages for food sources in the previous 10-year study. Inspections conducted by regulatory partners substantiated these findings.

Table 3 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	• Data Item #1 – Employees practice proper handwashing. • Data Item #2 – Employees do not contact RTE foods with bare hands.
Contaminated Equipment/ Protection from Contamination	• 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	• 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, RTE foods are properly date marked and discarded within 7 days of preparation or opening.
Inadequate Cooking	• Data Item #9 – Raw animal foods are cooked to required temperatures. • Data Item #10 – Cooked foods are reheated to required temperatures.

Data Items, Information Statements, and Documenting Observations

Using the 2013 version of the FDA Food Code, the data collector marked observations and findings on the data collection form in four compliance categories (see Appendix A). The data collector determined whether observations of employee food safety practices or behaviors contained in the information statements were:

- **In Compliance (IN):** One or more information statements that are part of the data item were recorded as in compliance, and none of the information statements that are part of the data item was recorded as out-of-compliance.
- **Out-of-compliance (OUT):** One or more information statements that are part of the data item were recorded as out-of-compliance.
- **Not Observed (NO):** None of the information statements that are part of the data item was recorded as in compliance or out-of-compliance, and one or more information statements that are part of the data item were recorded as not observed. The "NO" marking was used when an information statement is a usual practice in the food establishment, but the data collector did not observe the practice during the data collection.
- **Not Applicable (NA):** All information statements that are part of the data item were recorded as not applicable. The "NA" marking was used when a data item or information statement was not a function of the food establishment.

Calculating Compliance Percentages for Food Safety Behaviors/Practices

Each data item comprises information statements related to specific food safety behaviors/practices. If any food safety practice was observed to be out-of-compliance, then the overall data item was marked out-of-compliance.

Percent out-of-compliance observations for each data item represents the proportion of establishments where that data item was found out-of-compliance. If, for example, the data show 80% out-of-compliance for the proper cooling of foods, this means that there was at least one observation of improper cooling of foods in 8 out of 10 establishments where cooling of TCS foods was observed. The 80% score should not be interpreted to mean that foods were cooled improperly 80% of the time.

Calculating Compliance Percentages for Each Risk Factor

Each risk factor category encompasses a number of different food safety practices that take place in restaurants, and for which widely recognized, prevention-based controls exist which, when followed, may prevent or minimize the impact of foodborne illness outbreaks. If any data item that is part of a risk factor was marked "OUT," the risk factor was considered out-of-compliance. The following formula calculates the percentage of restaurants out-of-compliance for each risk factor:

$$\text{Percent Out-of-compliance} = \frac{\text{Total Number of Out-of-compliance Observations for the Data Item}}{\text{Total Number of Observations (IN and OUT) for the Data Item}} \times 100$$

Assessing Food Protection Manager Certification

During data collection, the data collector obtained information about the scope and type of food protection manager certification attained. An assessment was made to determine whether:

- A CFPM was employed at the restaurant
- A CFPM was present during data collection
- The PIC (as defined in the FDA Food Code) at the time of data collection was a CFPM

For each area listed above where restaurant personnel provided a "yes" response, the data collector made an attempt to verify the response by requesting to view a copy of the certificate. The data collector also noted whether the certification was obtained from:

- An American National Standards Institute (ANSI)-accredited food protection manager certification program[1]
- A food protection manager certification program that was not ANSI-accredited, such as one that may have been developed and administered by the state or local regulatory authority with inspection oversight for the establishment
- A source for which the establishment personnel could not provide documentation or specific reference

In addition, by interviewing the PIC, the data collector determined whether it was the restaurant's policy to have a food protection manager present at all times in order to gather baseline information on restaurants that have such a policy in place.

Assessing Food Safety Management Systems

While FSMS vary across the retail and food service industry, consistent components include procedures, training, and monitoring (PTM). For the purpose of this study, these three key elements were used to assess an establishment's FSMS:

1 The American National Standards Institute (ANSI) provides independent third-party evaluation and accreditation of certification bodies determined to be in conformance with the *Standards for Accreditation of Food Protection Manager Certification Programs* available from the Conference for Food Protection (CFP). A food employee certified by a food protection manager certification program that is evaluated and listed by a CFP-recognized accrediting agency as conforming to the CFP Standards is deemed to comply with the 2013 FDA Food Code, §2-102.12, Certified Food Protection Manager.

- **Procedures (P):** A defined set of actions adopted by food service management 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 within the establishment 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

Taken collectively, these elements are referred to as an establishment's "PTM" rating.

Data collectors assessed each restaurant's FSMS to determine the extent to which it was developed and implemented. The risk factor for which a FSMS assessment was conducted in each restaurant was randomly selected based on the four foodborne illness risk factors, and 10 primary data items shown in Table 3.

For each of three FSMS key elements, the data collector interviewed the PIC to determine if the assessment criteria for the assigned foodborne illness risk factor were addressed. The assessment criteria focused on determining if:

- Management is able to describe the critical limits for (*the specific risk factor procedure or practice*) as they apply to the restaurant.
- Management is able to describe the steps/tasks (how and when) that are performed to ensure the identified critical limits for (*the specific risk factor procedure or practice*) are achieved.
- Management is able to identify specific employees that have been assigned the responsibility to correctly perform (*the specific risk factor procedure or practice*).
- Management is able to produce written materials (standard operating procedures, posters, wall charts, wallet cards, etc.) that support implementing the system to control (*the specific risk factor procedure or practice*) within the restaurant.

Based on management responses for each area described above, the data collector used a standardized system to rate each FSMS element (PTM).

For this study, rating numbers (1 through 4) were defined as follows:

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.

The study calculated a single overall PTM rating for each restaurant by adding all individual PTM ratings for each data item and dividing by the number of individual ratings given.

The FSMS score can be treated as a continuous variable with possible values ranging from 1 (complete absence of management systems) to 4 (well-developed and documented management systems). The score may also be analyzed as a categorical variable as illustrated in Table 4:

Table 4 Food Safety Management System Category by Score

Category	Score
Nonexistent	≤1
Underdeveloped	1 to <3
Well-developed	3 to <4
Well-developed and documented	4

To illustrate, if the poor personal hygiene risk factor was selected as the area for the data collector to conduct a FSMS assessment, then a separate evaluation of PTM would have been conducted for data items 1 and 2.

Example: Poor Personal Hygiene

Data Item #1 – Employees practice proper handwashing
Data Item #2 – Employees do not contact RTE foods with bare hands

If the ratings for PTM for data item #1 were 2 (P), 3 (T), and 3 (M), respectively, and for data item #2 the ratings were 2 (P), 2 (T), and 3 (M), the cumulative PTM rating for this establishment would be calculated as follows:

2 + 3 + 3 + 2 + 2 + 3 = 15

$$\frac{\text{Total of individual ratings of the six PTM elements evaluated}}{\text{Number of PTM elements evaluated}} = \frac{15}{6} = 2.5$$

The cumulative PTM score for this restaurant is 2.5.

Quality Assurance

Data collected were stored in a database developed specifically for this study. This database contained a pre-programmed series of quality assurance checks to verify the accuracy of the data each time data was entered. Examples of the type of quality assurance checks programmed into the database include the following:

- Notifications via dialogue boxes when any data entry field has been inadvertently left blank.
- Standard drop-down screens for consistent responses to informational data entry fields.
- Automatic calculation of the results of the overall data item based on the markings entered for the information statements under the data items.
- Cross-checks to ensure that compliance marking for data items requiring temperature measurements were consistent with the temperatures recorded in the temperature charts.
- Automatic calculations for food product temperature summary tables based on the actual temperature recorded in the temperature chart as compared to the required food safety temperature for the data item.
- Notifications via dialogue boxes that ensure the FSMS assessment was entered for the selected risk factor area.

Statistical Analysis

Statistical analysis of the data was performed utilizing JMP©, Version 16. Statistical significance of individual variables was determined at $p < 0.05$ to understand the relative effect of each variable on the out-of-compliance status of data items. The data was also analyzed by running descriptive statistics to describe the sampled population. Correlation analysis was conducted to identify relationships between variables. The impact of the presence of a CFPM and/or FSMS on the out-of-compliance data items was tested using multiple regression analysis. For each significant result, the moderating effect of multiple-unit status and complexity of food preparation was tested using multi-factor analysis of variance (ANOVA).

RESULTS AND DISCUSSION

Descriptive Statistics

This study included 421 fast -ood restaurants and 430 full-service restaurants.

- Risk category and status as a multiple-unit operation differed between fast-food and full-service restaurants. Eighty percent of fast-food restaurants were risk category 2, whereas 86% of full-service restaurants were risk category 3.

- The majority of fast-food restaurants (75%) were part of a multiple-unit operation, whereas the majority of full-service operations (64%) were not.
- Forty five percent of fast-food restaurants had well-developed and well-developed and documented FSMS, as opposed to only 13% of full-service restaurants.
- In fast-food restaurants that were part of multiple-unit operations, 58.3% of establishments had well-developed or well-developed and documented FSMS, as compared to only 6.8% of single-unit establishments. Full-service restaurants had values of 28.3% and 3.6%, respectively.

As shown in Table 5, the majority of establishments in the present study had either a PIC that was a CFPM or no CFPM at all. Sixty-six percent of fast-food restaurants had a PIC present at the time of data collection, whereas 19% had no CFPM at all. In full-service restaurants, 57% had a PIC present at the time of data collection, as opposed to 26% with no CFPM.

Table 5 Descriptive Statistics

Characteristic	Number of Fast-Food Restaurants (N = 421)	%	Number of Full-service Restaurants (N = 430)	%
Certified Food Protection Manager				
None	80	19.00	111	25.81
Employed but not present	53	12.59	60	13.95
Employed and present	9	2.14	16	3.72
Person in charge	279	66.27	243	56.51
Food Safety Management System*				
Nonexistent	41	10.02	91	21.16
Underdeveloped	183	44.74	285	66.28
Well-developed	136	33.25	43	10.00
Well-developed and documented	49	11.98	11	2.56
Risk Categorization				
Risk category 2	336	79.81	51	11.86
Risk category 3	85	20.19	370	86.05
Risk category 4	0	0.00	9	2.09

Characteristic	Number of Fast-Food Restaurants (N = 421)	%	Number of Full-service Restaurants (N = 430)	%
Multiple-unit				
Yes	315	74.82	156	36.28
No	106	25.18	274	63.72

** There were 12 establishments that were not evaluated was due to data items randomly selected for the PTM evaluation were not applicable to the facility; therefore, a FSMS score could not be calculated. Additional data items were not assigned for evaluation of PTM if the first set of randomly selected data items could not be evaluated.*

It is worth noting that the majority of all restaurants in this study operated in jurisdictions enrolled in the PS, but the majority of those jurisdictions did not meet Program Standard 1, which applies to the regulatory foundation used by a retail food program (Table 6). Most restaurants also operated in jurisdictions that used grading and scoring systems, publicly posted inspection results, and had a requirement that establishments must have a CFPM (Table 6).

Table 6 Jurisdictional Characteristics

Characteristic	Number of Fast-Food Restaurants (N = 425)	%	Number of Full-service Restaurants (N = 396)	%
Jurisdiction enrolled in Program Standards				
Yes	330	78.38	316	73.49
No	91	21.62	114	26.51
Jurisdiction meets Program Standards Standard 1				
Yes	79	23.94	79	25.00
No	251	76.06	237	75.00
Jurisdiction uses a grading system				
Yes	240	57.01	247	57.44
No	181	42.99	183	42.56
Jurisdiction requires public posting of inspection results				
Yes	308	73.16	324	75.35
No	113	26.84	106	24.65
Jurisdiction has mandatory Certified Food Protection Manager requirement				
Yes	305	72.45	298	69.30
No	116	27.55	132	30.70

Occurrence of Risk Factors and Out-of-Compliance Data Items

Percent Out-of-compliance

The occurrence of foodborne illness risk factors and the associated food safety behaviors/practices was studied among 851 restaurants (421 fast food and 430 full-service). Table 7 shows the percentage of restaurants found out-of-compliance for each risk factor. The two most commonly occurring risk factors found out-of-compliance in both types of restaurants were improper holding (fast food, 77%; full-service restaurants, 94%) and poor personal hygiene (fast food, 61%; full-service restaurants, 77%). Inadequate cooking was the least out-of-compliance risk factor found in both fast food (12%) and full-service restaurants (30%). This practice/behavior (cooking raw animal foods) was observed in 61% of fast-food restaurants (255/421) and in 82% of full-service restaurants (351/430). The timing of the data collection visit may have influenced the specialist's ability to observe this risk factor as reheating of cooked foods to required temperatures (a data item included under the foodborne illness risk factor of inadequate cooking) is often one of the first thermal processes conducted in a restaurant as part of its pre-opening procedures.

The high out-of-compliance percentage of the improper holding risk factor (Table 7) in fast-food restaurants (77%) was largely due to high out-of-compliance findings in two of the four data items the risk factor includes: data items 5 (foods requiring refrigeration are held at proper temperature) and 7 (foods are cooled properly). These data items had out-of-compliance percentages of 62% and 59%, respectively.

The high out-of-compliance percentage of the improper holding risk factor (Table 7) in full-service restaurants (94%) was largely due to high out-of-compliance findings in three of the four data items that the risk factor includes: data items 5 (foods requiring refrigeration are held at proper temperature), 7 (foods are cooled properly), and 8 (refrigerated, RTE foods are properly date marked and discarded within seven days of preparation or opening). These data items had out-of-compliance percentages of 80%, 69%, and 64%, respectively.

Table 7 Risk Factors Out-of-Compliance

Foodborne Illness Risk Factor	Fast-Food Restaurants (# OUT)	Total Obs. (IN & OUT)	% OUT	Full-service Restaurants (# OUT)	Total Obs. (IN & OUT)	% OUT
Poor Personal Hygiene	257	421	61.05	330	430	76.74
Contaminated Equipment	221	421	52.49	327	430	76.05
Improper Holding/Time and Temperature	323	421	76.72	406	430	94.42
Inadequate Cooking	31	255	12.16	104	351	29.63

Table 8 shows the percentage of restaurants found out-of-compliance for each of 10 primary data items. Raw animal foods cooked to required temperatures was the least-occurring primary data item out-of-compliance in both fast-food and full-service restaurants.

The out-of-compliance finding with handwashing (data item 1; 59%) in fast-food restaurants (Table 8) was due to at least one observation in 46% of fast-food restaurants that an employee did not clean and wash their hands at the required time, and in 39% of fast-food restaurants that at least one employee was not properly cleaning and washing their hands.

The high out-of-compliance finding with handwashing (data item 1; 74%) in full-service restaurants (Table 8) was due to at least one observation in 67% of full-service restaurants that an employee did not clean and wash their hands at the required time, and in 48% of full-service restaurants that at least one employee was not properly cleaning and washing their hands.

Table 8 Total Number and Percentage of Restaurants Out-of-Compliance for Each Data Item

Data Item	Description	Fast-Food Restaurants (# OUT)	Total Obs. (IN & OUT)	% OUT	Full-service Restaurants (# OUT)	Total Obs. (IN & OUT)	% OUT
1	Employees practice proper handwashing	247	421	58.67	320	430	74.42
2	Employees do not contact RTE foods with bare hands	35	421	8.31	105	430	24.42
3	Food is protected from cross contamination during storage, preparation, and display	127	421	30.17	247	430	57.44
4	Food contact surfaces are properly cleaned and sanitized	166	421	39.43	247	430	57.44
5	Foods requiring refrigeration are held at proper temperature	262	421	62.23	343	430	79.77
6	Foods displayed or stored hot are held at proper temperature	78	316	24.68	113	361	31.30
7	Foods are cooled properly	87	148	58.78	175	254	68.90
8	Refrigerated, RTE foods are properly date marked and discarded within 7 days of preparation or opening	136	393	34.61	268	418	64.11

Data Item	Description	Fast-Food Restaurants (# OUT)	Total Obs. (IN & OUT)	% OUT	Full-service Restaurants (# OUT)	Total Obs. (IN & OUT)	% OUT
9	Raw animal foods are cooked to required temperatures	10	212	4.72	69	324	21.30
10	Cooked foods are reheated to required temperatures	22	84	26.19	42	118	35.59

As shown in Table 9, of the 10 food safety behaviors/practices (data items) associated with the four risk factors in this study, both fast-food and full-service restaurants were found to have the most control and least control over the same five data items. Data items 2 (employees do not contact RTE foods with bare hands) and 9 (raw animal foods are cooked to required temperatures) were found out-of-compliance least commonly at 8% and 5%, respectively, for fast-food restaurants, and 24% and 21%, respectively, for full-service restaurants. Data items 5 (foods requiring refrigeration are held at proper temperature), 1 (employees practice proper handwashing) and 7 (Foods are cooled properly) were found out-of-compliance most commonly at 62%, 59% and 59%, respectively, for fast-food restaurants, and 80%, 74% and 69%, respectively, for full-service restaurants. This suggests that while restaurants are better at managing bare-hand contact with RTE foods and ensuring foods are cooked to required temperatures, there remains a need to gain better control over cold holding foods requiring refrigeration, cooling foods and employee handwashing

Table 9 Primary Data Items Out-of-compliance in Descending Order of Percentage

Data Item	Fast-Food Restaurants Data Item Description	% OUT	Data Item	Full-service Restaurants Data Item Description	% OUT
5	Foods requiring refrigeration are held at proper temperature	62.23	5	Foods requiring refrigeration are held at proper temperature	79.77
7	Foods are cooled properly	58.78	1	Employees practice proper handwashing	74.42
1	Employees practice proper handwashing	58.67	7	Foods are cooled properly	68.90
4	Food contact surfaces are properly cleaned and sanitized	39.43	8	Refrigerated, RTE foods are properly date marked and discarded within 7 days of preparation or opening	64.11
8	Refrigerated, RTE foods are properly date marked and discarded within 7 days of preparation or opening	34.61	3	Food is protected from cross contamination during storage, preparation, and display	57.44

Data Item	Fast-Food Restaurants Data Item Description	% OUT	Data Item	Full-service Restaurants Data Item Description	% OUT
3	Food is protected from cross contamination during storage, preparation, and display	30.17	4	Food contact surfaces are properly cleaned and sanitized	57.44
10	Cooked foods are reheated to required temperatures	26.19	10	Cooked foods are reheated to required temperatures	35.59
6	Foods displayed or stored hot are held at proper temperature	24.68	6	Foods displayed or stored hot are held at proper temperature	31.30
2	Employees do not contact RTE foods with bare hands	8.31	2	Employees do not contact RTE foods with bare hands	24.42
9	Raw animal foods are cooked to required temperatures	4.72	9	Raw animal foods are cooked to required temperatures	21.30

Number of Data Items Out-of-compliance per Restaurant

Tables 10 and 11 list the cumulative number of restaurants found out-of-compliance by the number of data items. The tables also display the corresponding percentage, and cumulative percentages.

Fast-Food Restaurants

- Median number of primary data items out-of-compliance = 3
- 68% of restaurants (285) had 3 or fewer primary data items out-of-compliance
- 8% of restaurants (32) had no primary data items out-of-compliance
- 20% of restaurants (85) had one primary data item out-of-compliance

Full-service Restaurants

- Median number of primary data items out-of-compliance = 5
- 69% of restaurants (297) had 5 or fewer primary data items out-of-compliance
- 2% of restaurants (8) had no primary data items out-of-compliance
- 4% of restaurants (19) had one primary data item out-of-compliance

Table 10 Overall Number of Primary Data Items Out-of-Compliance Percentile (Fast-Food Restaurants)

Number of Primary Data Items Out-of-compliance	Number of Fast-Food Restaurants	%	Cumulative Number of Fast-Food Restaurants	Cumulative %
0	32	7.60	32	7.60
1	85	20.19	117	27.79
2	82	19.48	199	47.27
3	**86**	**20.43**	**285**	**67.70**
4	59	14.01	344	81.71
5	48	11.40	392	93.11
6	17	4.04	409	97.15
7	11	2.61	420	99.76
8	1	0.24	421	100.00
9	0	0.00	421	100.00
10	0	0.00	421	100.00

Table 11 Median Number of Primary Data Items Out-of-Compliance Percentiles (Full-service Restaurants)

Number of Primary Data Items Out-of-compliance	Number of Full-service Restaurants	%	Cumulative Number of Full-service Restaurants	Cumulative %
0	8	1.86	8	1.86
1	19	4.42	27	6.28
2	43	10.00	70	16.28
3	63	14.65	133	30.93
4	78	18.14	211	49.07
5	**86**	**20.00**	**297**	**69.07**
6	69	16.05	366	85.12
7	38	8.84	404	93.95
8	21	4.88	425	98.84

Number of Primary Data Items Out-of-compliance	Number of Full-service Restaurants	%	Cumulative Number of Full-service Restaurants	Cumulative %
9	5	1.16	430	100.00
10	0	0.00	430	100.00

Fast-Food Restaurants

A. Multiple-unit Operations

Restaurants that were part of an operation with two or more units were classified as multiple-unit operations. On average fast-food restaurants that were part of a multiple-unit operation had significantly lower primary data items out-of-compliance ($p < 0.05$) compared to those not part of a multiple-unit operation (Table 12).

Table 12 Mean Number of Primary Data Items Out-of-Compliance by Multiple-unit Operation Status (Fast-Food Restaurants)

Multiple-unit	Number of Fast Food Restaurants	Mean Number of Primary Data Items Out-of-compliance
No	106	3.82
Yes	315	2.43

B. Risk Categorization

On average risk category 2 establishments had significantly lower primary data items out-of-compliance ($p < 0.05$) compared to risk category 3 establishments (Table 13).

Table 13 Mean Number of Primary Data Items Out-of-Compliance by Risk Category (Fast-Food Restaurants)

Risk Category	Number of Fast-Food Restaurants	Mean Number of Primary Data Items Out-of-compliance
2	336	2.59
3	85	3.54

C. Grading, Inspection Reporting, and Food Handler Training

On average fast-food restaurants located in jurisdictions that graded establishments did not have significantly different results ($p = 0.4875$) compared to those located in jurisdictions that did not grade (Table 14). Establishments located in jurisdictions where there was a requirement to make inspection

results public did not have significantly different compliance (p = 0.6793) than those without inspection reporting. Establishments in jurisdictions that required food handler training did not have significantly different compliance (p = 0.6501) than establishments in jurisdictions that did not require food handler training.

Table 14 Mean Number of Primary Data Items Out-of-Compliance by Jurisdiction Variable (Fast-Food Restaurants)

Variable	Number of Fast-Food Restaurants	Mean Number of Primary Data Items Out-of-compliance
Grading		
No	181	2.71
Yes	240	2.83
Inspection Reporting		
No	113	2.84
Yes	308	2.76
Food Handler Training Requirement		
No	261	2.75
Yes	160	2.83

D. Certified Food Protection Managers

The only statistically significant finding for this variable in fast-food restaurants was between CFPM present and in charge and those with no CFPM. This indicates a significant difference in the number of out-of-compliance data items between establishments with a CFPM present and in charge (2.62) those that did not have a CFPM present and in charge (3.20) at the time of data collection, as indicated in Table 15.

Only 9 establishments were observed with a CFPM employed and present but not in charge, the difference in the average number of data items out-of-compliance was not significantly different between this status and no CFPM employed as well as CFPM employed (p = 0.4533 and p = 0.2673 respectively).

Table 15 Mean Number of Primary Data Items Out-of-Compliance by Certified Food Protection Manager Status (Fast-Food Restaurants)

Certified Manager Employed	Certified Manager Present	Certified Person in Charge	Number of Fast-Food Restaurants	Mean Number of Primary Data Items Out-of-Compliance
No	No	No	80	3.20
Yes	No	No	53	2.85
Yes	Yes	No	9	3.67
Yes	Yes	Yes	279	2.62

Full-service Restaurants

A. Multiple-unit Operations

Restaurants part of an operation with two or more units were classified as multiple-unit operations. On average full-service restaurants that were part of a multiple-unit operation had significantly lower primary data items out-of-compliance ($p < 0.05$) compared to those not part of a multiple-unit operation (Table 16).

Table 16 Mean Number of Primary Data Items Out-of-Compliance by Multiple-unit Operation Status (Full-service Restaurants)

Multiple-unit	Number of Full-service Restaurants	Mean Number of Primary Data Items Out-of-Compliance
No	274	4.82
Yes	156	3.89

B. Risk Categorization

On average risk category 2 establishments had significantly lower primary data items out-of-compliance ($p < 0.05$) compared to risk category 3 establishments (Table 17). Only 9 full-service restaurants were designated as risk category 4, so statistical comparisons were not performed.

Table 17 Mean Number of Primary Data Items Out-of-Compliance by Risk Category (Full-service Restaurants)

Risk Category	Number of Full-service restaurants	Mean Number of Primary Data Items Out-of-Compliance
2	51	3.84
3	370	4.60

C. Grading, Inspection Reporting, and Food Handler Training

Full-service restaurants located in jurisdictions that graded establishments did not have significantly different results (p = 0.7505) compared to full-service restaurants located in jurisdictions that did not grade. Establishments located in jurisdictions where there was a requirement to make inspection results public did not have significantly different compliance (p = 0.1377) than establishments in jurisdictions that did not require reporting. Establishments in jurisdictions that required food handler training did have significantly different compliance (p = 0.0406) than establishments in jurisdictions that did not require food handler training (Table 18).

Table 18 Mean Number of Primary Data Items Out-of-compliance by Jurisdiction Variables (Full-service Restaurants)

Variable	Number of Full-service Restaurants	Mean Number of Primary Data Items Out-of-Compliance
Grading		
No	183	4.45
Yes	247	4.51
Inspection Reporting		
No	106	4.73
Yes	324	4.41
Food Handler Training		
No	263	4.64
Yes	167	4.25

D. Certified Food Protection Managers

The only statistically significant finding for this variable in full-service restaurants was between CFPM present and in charge and those with no CFPM. This indicates a significant difference in the number of out-of-compliance data items between establishments with a CFPM present and in charge (4.16) versus those that did not have a CFPM present and in charge (4.82) at the time of data collection, as indicated in Table 19.

Only 16 establishments were observed with a CFPM employed and present but not in charge, the difference in the average number of data items out-of-compliance was not significantly different between this status and no CFPM employed as well as CFPM employed (p = 0.6984 and p = 0.1504 respectively).

Table 19 Mean Number of Primary Data Items Out-of-Compliance by Certified Food Protection Manager Status (Full-service Restaurants)

Certified Manager Employed	Certified Manager Present	Certified Person in Charge	Number of Full-service Restaurants	Mean Number of Primary Data Items Out-of-compliance
No	No	No	111	4.82
Yes	No	No	60	4.93
Yes	Yes	No	16	5.50
Yes	Yes	Yes	243	4.16

Correlations

Tables 20 and 21 present the correlations between different factors. For fast-food and full-service establishments FSMS were most highly correlated with multiple unit status, CFPM, data items and risk factors OUT-of-compliance. The positive correlation with CFPM indicates that as the CFPM category increases, the FSMS also increase.

FSMS were negatively correlated with the number of primary data items out-of-compliance. This negative correlation indicates that as the FSMS score increases, the number of primary data items out of compliance decreases.

Table 20 Pearson Product Correlations Between Study Variables (Fast Food)

Row	Risk Factors Sum (OUT)	Primary Data Items Sum (OUT)	FSMS Score	Uses a Grading System	Program Includes Public Reporting	Mandatory Food Protection Manager	Establishment is Part of Multi-Unit	Enrolled Program Standards	Requires Food Handler Card	Certified Manager	Risk Category
1. Risk factors Sum(OUT)	1.0000										
2. Primary Data Items Sum(OUT)	0.8665	1.0000									
3. FSMS Score	-0.4561	-0.5159	1.0000								
4. Uses a Grading System	0.0317	0.0329	0.0961	1.0000							
5. Program Includes Public Reporting	-0.0195	-0.0213	0.0730	0.2860	1.0000						
6. Mandatory Food Protection Manager	-0.0092	0.0011	0.0288	0.0873	-0.0496	1.0000					
7. Establishment is Part of Multi-Unit	-0.2676	-0.3446	0.5505	0.1153	0.0562	-0.0270	1.0000				
8. Enrolled Program Standards	0.0276	0.0030	0.0813	0.1151	0.4242	-0.1689	0.0676	1.0000			
9. Requires Food Handler Card	-0.0493	0.0233	0.0781	0.2747	0.2976	-0.1524	-0.0532	0.1853	1		
10. Certified Manager	-0.1129	-0.1277	0.2193	0.0209	-0.0577	0.4314	0.1136	-0.0735	-0.1787	1.0000	
11. Risk Category	0.0702	0.2186	-0.1576	-0.0055	-0.0025	-0.0607	-0.2808	-0.0665	-0.0281	0.0128	1.0000

Table 21 Pearson Product Correlations Between Study Variables (Full-service Restaurants)

Row	Risk Factors Sum (OUT)	Primary Data Items Sum (OUT)	FSMS Score	Uses a Grading System	Program Includes Public Reporting	Mandatory Food Protection Manager	Establishment is Part of Multi-Unit	Enrolled Program Standards	Requires Food Handler Card	Certified Manager	Risk Category
1. Risk factors Sum(OUT)	1.0000										
2. Primary Data Items Sum(OUT)	0.7881	1.0000									
3. FSMS Score	-0.2684	-0.4044	1.0000								
4. Uses a Grading System	0.0401	0.0145	0.0000	1.0000							
5. Program Includes Public Reporting	-0.0681	-0.0713	0.0976	0.4244	1.0000						
6. Mandatory Food Protection Manager	0.1419	0.1129	0.0174	-0.0120	-0.0180	1.0000					
7. Establishment is Part of Multi-Unit	-0.1261	-0.2329	0.4179	0.0625	0.0500	0.0408	1.0000				
8. Enrolled Program Standards	0.0317	0.0039	0.1297	0.0904	0.2310	-0.2056	0.1354	1.0000			
9. Requires Food Handler Card	-0.1076	-0.0994	0.0897	0.2999	0.2786	-0.1111	0.0637	0.1111	1		
10. Certified Manager	-0.0417	-0.1661	0.3270	-0.0665	0.0016	0.4641	0.2360	-0.0254	-0.1192	1.0000	
11. Risk Category	0.0143	0.0750	-0.0360	-0.0245	0.2310	0.0434	0.0032	0.0126	0.0174	0.0353	1.0000

Regression

To examine effects on the average number of primary data items out-of-compliance, FDA conducted regression analyses to determine whether risk category, multiple-unit status, CFPM, and/or FSMS were significant predictors of out-of-compliance data items.

Fast-Food Restaurants

There was a significant difference in the mean number of primary data items out-of-compliance between the different variables as determined by multi-factor ANOVA ($F(6,402) = 27.60$, $p < 0.01$). Table 22 presents the results of the effects tests, which test the null hypothesis that all parameters associated with the effect are zero.

Table 22 Effects Tests (Fast Food)

Variable	Number of Parameters	Degrees of Freedom (df)	Sum of Squares	F Ratio	P-value
Risk Category	1	1	17.62	7.92	0.0051*
Multiple-unit	1	1	1.65	0.74	0.3902
CFPM	3	3	6.14	0.92	0.4311
FSMS	1	1	184.62	82.99	<0.0001*

*p < 0.05 CFPM – Certified Food Protection Manager, FSMS – Food Safety Management System CFPM treated as ordinal variable, 1=none, 2=employed but not present, 3=present, 4=PIC FSMS.
Treated as continuous variable, possible values from 1-4.

Table 23 presents the results of the regression analysis. Risk category was a significant predictor of out-of-compliance data items in fast-food restaurants ($B = 0.54$, $t(1) = 2.81$, $p = 0.0051$). Multiple-unit status ($b = 0.09$, $t(1) = 0.86$, $p = 0.3902$) was not a significant predictor of out-of-compliance data items. FSMS ($B = -0.85$, $t(1) = -9.11$, $p < 0.01$) was found to be a significant predictor and negatively related to out-of-compliance data items. The negative parameter estimate for FSMS indicates that for every increase in the FSMS category there is a reduction of 0.85 in the number of primary data items out-of-compliance. CFPM was not a significant predictor of out-of-compliance data items.

Table 23 Regression Analysis (Fast Food)

Predicting Variable	B	Standard Error	t	p
Risk Category	0.54	0.19	2.81	0.0051*
Multiple-unit: No	0.09	0.10	0.86	0.3902
CFPM: None	-0.16	0.19	-0.84	0.4011
CFPM: Employed	-0.08	0.21	-0.40	0.6927
CFPM: Present	0.50	0.38	1.32	0.1886
FSMS	-0.85	0.09	-9.11	<0.0001*

*p < 0.05; Dependent Variable: Number of Data Items Out-of-compliance, CFPM – Certified Food Protection Manager, FSMS – Food Safety Management System

Full-service Restaurants

In full-service restaurants, there was a significant difference in the mean number of primary data items out-of-compliance between the different variables as determined by one-way ANOVA ($F(7,422) = 14.54$, $p < 0.01$). Table 24 presents the results of the effects tests, which tests the null hypothesis that all parameters associated with the effect are zero. This significant finding is further described by the regression analysis presented in Table 23.

Table 24 Effects Tests (Full-service Restaurants)

Variable	Number of Parameters	Degrees of Freedom (df)	Sum of Squares	F Ratio	Prob > F
Risk Category	2	2	26.14	4.29	0.0144*
Multiple-unit	1	1	5.67	1.86	0.1736
CFPM	3	3	12.59	1.38	0.2494
FSMS	1	1	155.25	50.91	<0.0001*

*p < 0.05; Dependent Variable: Number of Data Items Out-of-compliance, CFPM – Certified Food Protection Manager, FSMS – Food Safety Management System CFPM treated as ordinal variable, 1=none, 2=employed but not present, 3=present, 4=PIC FSMS. Treated as continuous variable, possible values from 1-4.

Table 25 presents the results of the regression analysis. Risk category (3-2) (B = 0.63, t (1) = 2.40, p = 0.0169) and FSMS (B = -0.87, t (1) = -7.13, p < 0.01) were significant predictors of out-of-compliance data items in full-service restaurants. The negative parameter estimate for the FSMS indicates that for every increase in the FSMS, there is a reduction of 0.87 in the number of primary data items out-of-compliance. Multiple-unit status and CFPM were not significant predictors of out-of-compliance data items (Table 25).

Table 25 Regression Analysis (Full service)

Predicting Variable	B	Standard Error	t	P
Risk Category (3-2)	0.63	0.26	2.40	0.0169*
Risk Category (4-3)	-1.07	0.59	-1.81	0.0709
Multiple-unit: No	0.13	0.10	1.36	0.1736
CFPM: None	-0.20	0.18	-1.11	0.2680
CFPM: Employed	-0.11	0.21	-0.52	0.6026
CFPM: Present	0.60	0.34	1.79	0.0737
FSMS	-0.87	0.12	-7.13	<0.0001*

*p < 0.05; Dependent Variable: Number of Data Items Out-of-compliance, CFPM – Certified Food Protection Manager, FSMS – Food Safety Management System

Employee health policies were also evaluated in the data collection. Employee health policies are described in the Food Code as the responsibilities of the permit holder and food employees to report symptoms/diagnosis, and managing ill employees by way of exclusion and restriction criteria. The questions outlined in Table 26 describe how employee health policies were evaluated in this data collection. It was found from a previous data collection analysis that most restaurants have no employee health policy. However, restaurants with Food Code recommended employee health policy components had more developed FSMS (Liggans et al., 2021).

The incorporation of and adherence to employee health policies provides a foundation upon which to establish a FSMS, the specific set of actions or procedures to help achieve AMC over foodborne illness risk factors—aimed at preventing cross contamination from food employees. Prior data collections of the FDA Retail Risk Factor Study have found more developed FSMS associated with fewer out of compliance observations for important food safety behaviors and practices in restaurants. When data from this reporting period was analyzed, it indicated that as FSMS improve employee health questions 2-6 are more likely to be "Yes". This indicates that FSMS may be a promising tool in developing and implementing complete employee health policies (Figures 2 and 3).

Table 26 Employee Health Policy Questions On The Data Collection Form

Question No.	Question
Q1	Food employees exhibiting certain illness symptoms or conditions that require exclusion or restriction in the Food Code, **ARE OBSERVED** within the establishment during the data collection.
Q2	Are food employees and conditional employees informed of their responsibility to report to the person in charge illness **SYMPTOMS** as specified in Section 2-201.11 of the Food Code?
Q3	Are food employees and conditional employees informed of their responsibility to report to the person in charge diagnosis with, or exposure to, specific **ILLNESSES** specified in Section 2-201.11 of the Food Code?
Q4	Is management aware of its responsibility to **NOTIFY THE REGULATORY AUTHORITY** when a food employee is jaundiced or diagnosed with an illness due to a pathogen specified in Section 2-201.11 of the Food Code?
Q5	Is the management's employee health policy consistent with 2-201.12 of the Food Code for **EXCLUDING AND RESTRICTING** food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods?
Q6	Is the management's employee health policy consistent with 2-201.13 of the Food Code for **REMOVAL OF EXCLUSIONS AND RESTRICTIONS** of food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods?

Figure 2 Full-Service Restaurant Employee Health Policy Status by Food Safety Management System Category

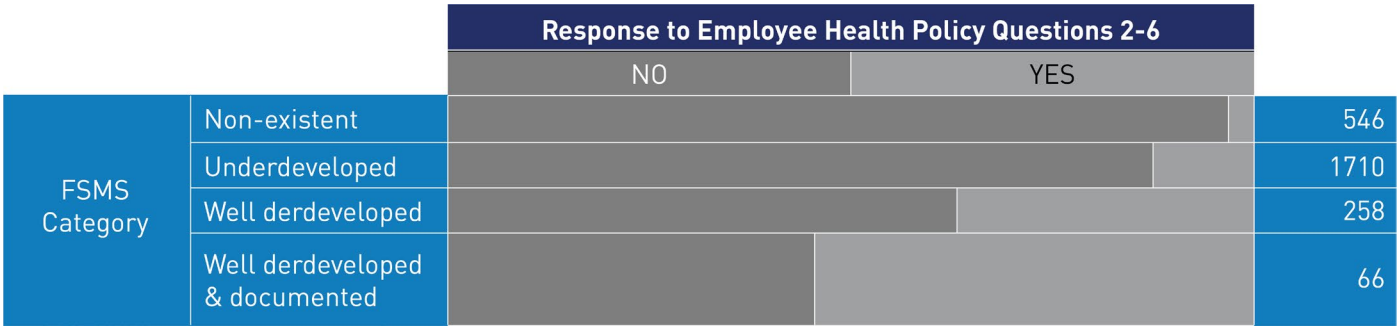
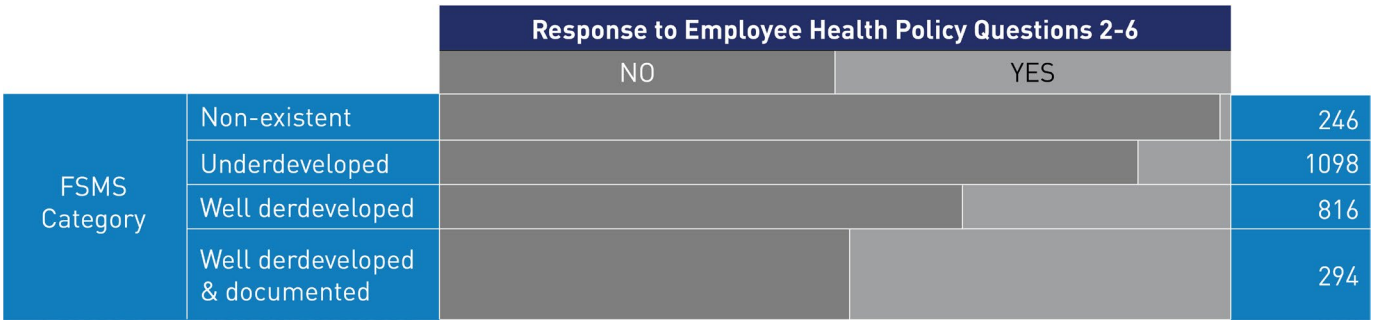


Figure 3 Fast-Food Restaurant Employee Health Policy Status by Food Safety Management System Category



For supplemental statistical analyses, please refer to Appendix E: Supplemental Statistical Analysis.

CONCLUSION

The purpose of this second restaurant data collection during the 2013-2023 study was to investigate the relationship between FSMS, CFPM, and the occurrence of risk factors and food safety behaviors/practices commonly associated with foodborne illness in restaurants.

Key findings included:

- Approximately 70% of the restaurants in this study operated in jurisdictions that required a CFPM and most restaurants (66.27% of fast food and 56.51% of full-service) were found to have a CFPM employed, present, and in charge at the time of data collection.
- Of the foodborne illness risk factors investigated in this study, 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.
- Of the food safety behaviors/practices investigated in this study, restaurants had the best control over the following:
  - Ensuring no bare-hand contact with RTE foods
  - Cooking raw animal foods to their required temperatures
- There remains a need to gain better control over the following food safety behaviors and practices:
  - Employee Handwashing (includes both when to wash and how to wash properly)
  - Cold holding of foods requiring refrigeration
  - Foods are cooled properly
- FSMS were the strongest predictor of data items being out-of-compliance in both fast-food and full-service restaurants: those with well-developed FSMSs had significantly fewer food safety behaviors/practices out-of-compliance than did those with “less developed” (underdeveloped and non-existent) FSMS.For example, fast -ood restaurants with nonexistent FSMS averaged 4.5 data items out-of-compliance, while fast-food restaurants with well-developed and documented FSMS averaged 1.5. For full-service restaurants, facilities with nonexistent FSMS averaged 5.3 data items out-of-compliance, while those with well-developed and documented FSMS averaged 2.2 data items out-of-compliance.
- Restaurants with a CFPM present and in charge at the time of data collection were associated with fewer out-of-compliance food safety behaviors/practices than those whose CFPM was not present and in charge, based upon univariate examination. However, upon multivariate examination, the correlations between certified food protection manager and out-of-compliance become non-significant, indicating that FSMSs and not the presence of a certified food protection manager predicts compliance with food safety behaviors/practices.

- Restaurants that had a CFPM who was the PIC at the time of data collection had significantly better FSMS scores than those restaurants that did not have a CFPM present or employed.
- In fast-food restaurants with a CFPM who was the PIC at the time of data collection, the average FSMS score was 2.80 while the average score for fast-food restaurants with no CFPM employed was 2.19. In full-service restaurants, scores were 2.18 and 1.62, respectively. This suggests that having a CFPM present at all hours of operation may enhance food safety management systems and reduce the number of out-of-compliance food safety behaviors/practices.

Areas of Future Study

Measuring and reporting on the occurrence of foodborne illness risk factors and food safety behaviors/practices in restaurants provide the foundation for identifying where risk-based interventions might have the greatest impact on enhancing public health protection. The FDA will continue to collect data on the occurrence of foodborne illness risk factors and use the results to aid decision makers in reducing the occurrence of risk factors responsible for causing foodborne illness. Continued research is needed to identify antecedents and root causes associated with poor food safety behaviors/practices in restaurants and to determine cost-effective, evidence-based intervention strategies and inspection approaches for improving the nation's retail food protection system.

Further study to understand the relationship between the number and type of employee health policy components and FSMS is needed. Additionally, the adoption of the Food Code employee health policy recommendations as regulatory requirements in retail food programs needs to be explored, along with identifying barriers associated with the development and implementation of such policies.

APPENDICES

APPENDIX A: FDA FOODBORNE ILLNESS RISK FACTOR STUDY DATA COLLECTION TOOLS

The following tools utilized in this study can be accessed online at https://www.fda.gov/retailfoodriskfactorstudy:

Protocol for the Risk Factor Study Data Collection or Study on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

Restaurant Data Collection Form

Marking Instructions for the Data Collection Form

APPENDIX B: DATA COLLECTION INTRODUCTION LETTER

Dear Owner/Manager:

Your facility has been randomly selected as part of a nationwide research project designed to assess food preparation procedures and practices specific to the various segments of the retail food industry. The U.S. Food and Drug Administration (FDA) will use this research for identifying best practices within the industry and directing limited resources to areas that will provide the most significant public health benefits.

This is not a regulatory visit. Your participation is voluntary. No inspection report will be left with your facility. This is a research project designed to focus on the implementation of food safety procedures and practices within the retail food industry that are designed to protect the public health. The expected length of the data collection will be 90-120 minutes. Approximate 30 minutes of the data collection will focus on obtaining information on the nature of your operation.

Should an observation be made of a food safety procedure or practice that poses a significant public health risk, every effort will be made to work with you to ensure that the appropriate corrective action is taken to alleviate the hazard. Should a situation arise where a significant public health risk cannot be resolved during the data collection, the regulatory authority that has issued your permit will be contacted to work with you to ensure corrective action is taken.

An exit briefing will be provided at the end of the visit to discuss significant findings that may assist you in enhancing the effectiveness of your food safety system. If significant food safety issues are identified, they will be brought to the attention of the person-in-charge or responsible employee to determine the appropriate corrective action based on the current FDA Food Code. Your questions regarding the data collection process or food safety issues in general are encouraged as part of the visit to your facility.

Your facility's name will not appear on any reports or public documents. The research project is designed to protect the privacy of participating establishments to the extent the law permits. The data collected is tabulated using broad industry segments and is not associated with any specific establishment.

FDA is responsible for providing technical assistance to approximately 75 state and territorial agencies and more than 2,300 local departments that assume primary responsibility for working with the industry on preventing foodborne illnesses. Beginning in 1998, FDA began collecting data related to direct observations made of food safety practices within institutional foodservice, restaurant, and retail food segments of the industry. From the data collected, FDA provides guidance to regulatory and industry food safety professionals to assist them in addressing food safety issues that have the most significant impact on protecting the public health.

FDA's previous research studies can be accessed and downloaded from the following web link:

https://www.fda.gov/retailfoodriskfactorstudy

Public Reporting burden of this collection of information is estimated to average 73 minutes per response for the PIC of a fast-food restaurant, 106 minutes for the person of charge of a full-service restaurant, and 30 minutes for the program director (or designated individual) of the regulatory authority. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850. PRAStaff@fda.hhs.gov. OMB Control #0910-0744. Expires September 30, 2018

Thank you for your willingness to cooperate in this important endeavor. It is through this type of cooperative effort that government and the food service industry seek to provide safe and wholesome food to the consuming public.

In the future, should you have any questions regarding this study or other food safety issues, please do not hesitate to contact me.

Sincerely,

[Data collector's contact information]

APPENDIX C: LIMITATIONS

Field Operations

Restaurants are dynamic. There is no set pattern of operation within a restaurant that will ensure all food safety practices and employee behaviors covered in this study will be observed by a data collector. Establishment type, the season of the year, the time of day, and the length of time available for each data collection are some of the factors that impacted direct observations of food safety practices within a restaurant. As an example, cooling foods requires a significant period of time to conduct a quantitative assessment of multiple temperature measurements to determine if the rate of cooling will conform to Food Code time/temperature critical limits. Reheating foods (captured under the foodborne illness risk factor of inadequate cooking) is often one of the first thermal processes

conducted in a restaurant as part of its pre-opening procedures. The timing of the data collection visit and the availability of cooked foods reheating to required temperatures are elements that influenced the data collector's ability to observe this data item.

A sufficient number of observations must be obtained based on the sample size to draw statistically significant conclusions. The FDA attempted to achieve this balance in the current design of the study by focusing the statistical analysis on 10 primary data items that had a high likelihood of being observed during the data collections and have been epidemiologically linked to foodborne illness outbreaks.

Focusing on the primary 10 data items during this retail food store collection period reduced the variations in observations of data items that occurred during the previous study. Of the 10 primary data items, 2 were more difficult to observe (occurred less frequently at the time of data collection) than the others:

- Data Item # 7 – Foods are properly cooled
- Data Item # 10 – Cooked foods are reheated to required temperatures

Study Design

Sample Design

Twenty-two FDA data collectors conducted the data collections at restaurants. The data collectors were geographically dispersed throughout the United States. The geographic distribution of data collectors throughout the U.S. allows for a broad sampling of establishments in all regions of the U.S.; therefore, establishments were randomly selected to participate in the study from among all eligible establishments located within a 150-mile radius of each data collector's home location.

The total number of establishments in the country was approximately 67,160 and the total number within the sampling zones was 42,159. Roughly 63% of all establishments in the restaurant segment were eligible for selection.

The current picture of compliance with the risk factors reflects the entire U.S. only to the extent that the facilities in the sampling zones are representative of the overall industry.

The data used in the selection process were purchased from the Environmental Systems Research Institute (ESRI), Inc. The restaurant data are part of ESRI's USA Business Locations and Business Summary. This dataset is updated annually, with the latest version updated in July 2014. The data are stored as a GeoDataBase, which is a collection of geographic datasets of various types held in a common file system folder, a Microsoft Access database, or a multi-user relational database management system.

ESRI and its partner, Infogroup, reference several sources, including directory listings such as

the Yellow Pages and business white pages; annual reports; 10Ks and Securities and Exchange Commission (SEC) information; federal, state, and municipal government data; business magazines; newsletters and newspapers; and information from the U.S. Postal Service. To ensure accurate and complete information, Infogroup conducts annual telephone verifications with each business listed in the database.

Restaurant addresses are geocoded to assign latitude and longitude coordinates to each site. The quality of the local address system varies. For instance, address matching is better in urban areas that use street-level address systems than in rural areas that might not. Restaurants that cannot be assigned to a census block group are assigned to a census tract or county. The geographic locations were used to perform spatial sampling for the risk factor study.

The geographical distribution of data collectors throughout the country, especially in relatively high-density population centers, allowed for a broad sampling throughout all regions of the U.S. The choice of data collection locations was based on the data collectors' geographical areas of responsibility and provided a reasonably convenient design for estimating national risk-related behaviors and practices.

This project was designed to examine patterns of the occurrence of foodborne illness risk factors within establishments using multiple data collection periods. The sample selection methodology and size of the dataset do not support comparisons of individual data collectors' geographical areas, states, cities, or even regions of the U.S.

In addition, the project is not designed to support comparisons of different chains of restaurants. There is no statistical justification for examining reduced sets of results particular to, for example, two chains of restaurants, and drawing conclusions from the differences.

Comparing Data over Time

The total number of observations for each data item is likely to change from one data collection period to another. Variation in the number of observations can make it difficult to draw statistical conclusions between any two data collection periods. Changes in the number of observations of data items may be attributed to the following:

- Sample variations
- Changes in industry practices

Sampling Variations

The frequency at which a data item can be observed during each data collection period may change due to sampling establishments within the same facility type that have different food products and procedures.

The FDA tracked the actual time spent to complete data collection at each restaurant. The average time

to complete data collection in full-service restaurants was 99.5 minutes and fast-food restaurants was 75.8 minutes. Travel time to and from the restaurant location and off-site data entry were not included as part of this FDA time assessment.

Changes in Industry Practices

If changes in an industry practice result in more inspectors marking "not applicable" (NA) rather than "in" or "out-of-compliance," there may be a change in the total number of observations for a given data item from one data collection period to the next. This may result in a corresponding change in the relative weight of that data item in the compliance percentage for the relevant risk factor.

For example, if numerous establishments have shifted from using raw shell eggs to using pasteurized egg products, the number of observations related to inadequate cooking will decrease from one data collection period to the next. Therefore, a lower out-of-compliance percentage for the inadequate cooking risk factor may not be reported, even though the new industry practice represents improved active managerial control.

APPENDIX D: DATA COLLECTION CYCLE FOR RESTAURANTS

To assess trends over time, a minimum of three data points is required. Data from this report will be used with subsequent data collections conducted in future data collections to determine trends in the occurrence of risk factors over the 10-year study period.

The first restaurant data collection period began in November 2013 and was completed in September 2014. This report highlights the statistically significant findings from the second restaurant data collection period from October 2017 through September 2018. Table 27 provides a summary of the 10-year study time frames for the restaurant data collection periods.

Table 27 Summary of Data Collection Time Frames for Restaurants

Industry	Facility Type	Initial Data Collection Period (Baseline Measurement)	2ND Data Collection Period	3RD Data Collection Period
Restaurants	Full-service Restaurants and Fast-Food Restaurant	Nov. 15, 2013 to Sept. 30, 2014	Oct. 1, 2017 to Sept. 30, 2018	Date to be determined upon return to normal field operations

APPENDIX E: SUPPLEMENTAL STATISTICAL ANALYSIS

The Biostatistics and Bioinformatics Staff analyzed the data utilizing a main effects multi-factor ANOVA. Findings concluded that the primary variable associated with improved compliance was FSMS. In the analysis for fast-food facilities, the establishments' risk categorization was also

predictive of the out-of-compliance rate. In the analysis for full-service facilities, the establishments' risk categorization, the requirement to have a CFPM, CFPM status and the regulatory authority's enrollment status in the PS were also predictive of the out-of-compliance rate. Full-service establishments in jurisdictions that were not enrolled in the PS had a lower percentage of out-of-compliance data items. Full-service establishments in jurisdictions that required a CFPM had higher percentage of out-of-compliance data items. When controlling for the 6 comparisons for CFPM there were no significant differences. There were statistically significant main effect P-values in the model for FSMS and risk category for both facility types.

Reasons for performing the regression analysis:

Many factors were measured in the study, and several have statistically significant ($p<0.05$) pairwise correlations with each other as seen in Tables 20 and 21. The purpose of the ANOVA is to determine whether a factor has remaining or additional explanatory power or association with the response of interest, in this case compliance status, when other predictor variables are also included in the model. The goal is to identify potentially spurious correlations. In our regression analysis, we want to determine which variables were predictive of improved compliance when the set of correlated predictors were in the model. If a pairwise correlation becomes non-significant in the ANOVA model, we state the pair-wise correlation was explained by other predictors and may be spurious.

Parameter analysis:

There are several variables that may affect the response variable "*number of primary data items out of compliance*". The multi-factor ANOVA model was run in JMP, Version 16 with all the variables. Then, each variable was removed from the full model in order to assess the effect on the change in model R-squared upon removal, presented in Tables 28 and 29. The R-squared represents the amount of variance in the response variable that was explained by the model. If there was minimal change in the model R-square upon removal of a predictor, it meant that the correlation between the response and the variable could be explained by other variables in the model. If there was a significant reduction in R-squared upon removal, it indicated that the predictor in question had statistical explanatory power that is not explained by the other variables. We also reported the P-values of the F statistic. P-values greater than 0.05 were not generally considered to be statistically significant. P-values less than 0.05 are bolded in Tables 28 and 29 and considered significant.

Table 28 Parameter Analysis (Fast food)

Fast Food	Model R- square	Reduction in R-Square	% R- square reduction	Prob > F
Model with all parameters	0.302085			
Management systems (FSMS)	0.156284	0.145801	48.26%	**<0.0001**

Fast Food	Model R- square	Reduction in R-Square	% R- square reduction	Prob > F
Multiple-Unit	0.301069	0.001016	0.34%	**0.4475**
Risk category	0.286694	0.015391	5.10%	<0.0033
Certified Manager (CFPM)	0.296637	0.005448	1.80%	0.3778
Enrolled in Program Standards	0.299721	0.002364	0.78%	0.2469
Jurisdiction requires CFPM	0.301251	0.000834	0.28%	0.4915
Jurisdiction requires grading	0.297809	0.004276	1.42%	0.1197
Jurisdiction requires reporting	0.299985	0.002100	0.70%	0.2752
Jurisdiction requires food handler card	0.300719	0.001366	0.45%	0.3786

Table 29 Parameter Analysis (Full service)

Full-service	Model R- square	Reduction in R- Square	% R- square reduction	Prob > F
Model with all parameters	0.233504			
Management systems (FSMS)	0.151548	0.081956	35.10%	**<0.0001**
Multiple-Unit	0.229488	0.004016	1.72%	0.1401
Risk category	0.217024	0.016480	7.06%	**0.0119**
Certified Manager (CFPM)	0.216962	0.016542	7.08%	0.0304
Enrolled in Program Standards	0.223156	0.010348	4.43%	**0.0181**
Jurisdiction requires CFPM	0.207414	0.026090	11.17%	0.0002
Jurisdiction requires grading	0.231360	0.002144	0.92%	**0.2807**
Jurisdiction requires reporting	0.232092	0.001412	0.60%	0.3813
Jurisdiction requires food handler card	0.229346	0.004158	1.78%	**0.1333**

Removing only the FSMS variable from the model resulted in a reduction of R-square of 48.26% and 35.10% respectively. Removing only the risk category variable resulted in a 5.10% and 7.06% reduction in R-squared respectively. For full-service restaurants CFPM category and being in a jurisdiction that requires a CFPM had effects of 7.08% and 11.17% respectively. The removal of any of the other variables from the model had a small effect on the R-square.

The average primary data items out-of-compliance for establishments with nonexistent FSMS was 4.5 and 5.2 respectively, while those with well-developed and documented FSMS had 1.5 and 2.2 respectively primary data items out-of-compliance. In this analysis, the predictor of FSMS was the predictor that had the most significant effect on the model predictions.

Relationship between CFPM and FSMS:

It is important to note that the CFPM category has a small effect on the number of data items out-of-compliance when FSMS are included in the model. However, there is evidence to suggest that the employment of a CFPM is correlated with improved FSMS.

There is a relationship between the CFPM status and the FSMS. For example, facilities that had a CFPM (who is the PIC) at the time of inspection had a far higher percentage of well-developed or well-developed and documented FSMS than those that had no CFPM employed. Facilities that had a CFPM present who was also the PIC accounted for a majority of the fast-food establishments with well-developed or well-developed and documented FSMS. If an establishment had no CFPM employed, it was more likely to have an underdeveloped or non-existent FSMS. Establishments with a CFPM who was the PIC were more likely to have well-developed or well-developed and documented FSMS.

These data are presented in Tables 30 and 31 below.

Table 30 Certified Manager Status by Food Safety Management System (Fast Food)

Certified Manager	FSMS Category Non-Existent (Number of restaurants)	FSMS Category Underdeveloped (Number of restaurants)	FSMS Category Well-Developed (Number of restaurants)	FSMS Category Well-Developed and Documented (Number of restaurants)
None	11.8% (9)	68.4% (52)	15.8% (12)	3.9% (3)
Employed	14.0% (7)	50.0% (25)	24.0% (12)	12.0% (6)
Present	11.1% (1)	44.4% (4)	44.4% (4)	0.0% (0)
PIC	8.8% (24)	37.2% (102)	39.4% (108)	14.6% (40)

Table 31 Certified Manager Status by Food Safety Management System (Full service)

Certified Manager	FSMS Category Non-Existent (Number of restaurants)	FSMS Category Underdeveloped (Number of restaurants)	FSMS Category Well-Developed (Number of restaurants)	FSMS Category Well-Developed and Documented (Number of restaurants)
None	30.6% (34)	64.0% (71)	5.4% (6)	0.0% (0)
Employed	33.3% (20)	65.0% (39)	1.7% (1)	0.0% (0)
Present	18.8% (3)	75.0% (12)	6.3% (1)	0.0% (0)
PIC	14.0% (34)	67.1% (163)	14.4% (35)	4.5% (11)

Analysis of Least Squares Means Used in the Regression Analysis

The multiple-unit effect can be seen when the least squares means are analyzed, presented in Tables 32 and 33. There was no significant difference ($p > 0.05$) in the number of primary data items out-of-compliance depending upon the facility status as a multiple-unit operation (both fast food and full-service). The least squares means were not significantly different for any level of CFPM. The risk category was significant ($p < 0.05$). Fast-food and full-service establishments that were risk category 2 had significantly lower primary data items out-of-compliance than those that were risk category 3.

Table 32 Least Squares Means (Fast Food)

Variable	Least Squares Means	Standard Error
Multiple-unit		
No	3.0	0.2217
Yes	2.9	0.1560
Risk category		
2	3.0	0.1605
3	3.5	0.2044
CFPM		
None	2.8	0.1870
Employed	2.9	0.2228
Present	3.5	0.5037
Person in charge	2.7	0.1169

Table 33 Least Squares Means (Full service)

Variable	Least Squares Means	Standard Error
Multiple-unit		
No	4.3	0.2778
Yes	4.0	0.2983
Risk category		
2	4.1	0.2713
3	4.8	0.1403
4	3.7	0.6004

Variable	Least Squares Means	Standard Error
CFPM		
None	3.9	0.2845
Employed	4.0	0.3308
Present	4.7	0.5023
Person in charge	3.8	0.2579

The plot of mean primary data items out-of-compliance by FSMS score and CFPM status, shown in Figures 4 and 5, shows the relationship between FSMS, CFPM status, and compliance. The primary data items out-of-compliance decreases as the FSMS improve. Most establishments in the study had CFPM who were also the PIC at the time of data collection. These are represented in orange and contain the most area in the plot. Most of the establishments that had well-developed or well-developed and documented management systems had a CFPM who was also the PIC at the time of data collection.

Figure 4 Plot of Mean Primary Data Items Out-of-Compliance by Food Safety Management System Category Fast food

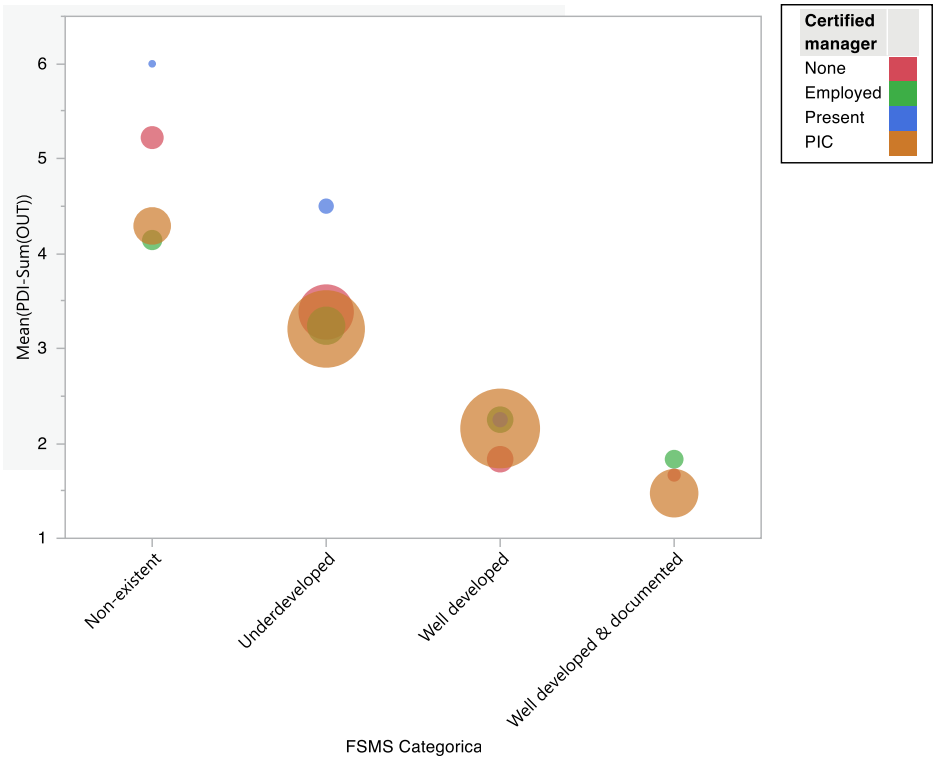
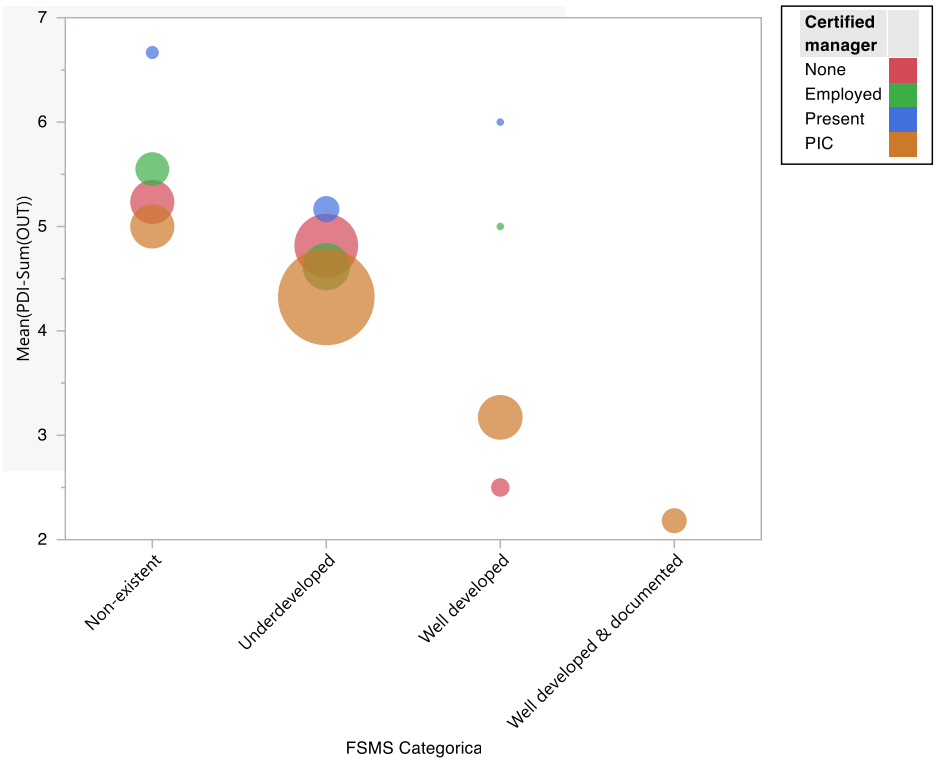


Figure 5 Plot of Mean Primary Data Items Out-of-Compliance by Food Safety Management System Category Full service



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