

**FDA REPORT ON THE
OCCURRENCE OF FOODBORNE ILLNESS
RISK FACTORS IN FAST FOOD AND FULL-
SERVICE RESTAURANTS,
2013-2014**

PREPARED BY THE FDA NATIONAL RETAIL FOOD TEAM

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Food service managers of the restaurants selected for the study for their cooperation and assistance during the data collections.

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CONTENTS

LIST OF TABLES.....	i
LIST OF FIGURES.....	iii
Abstract.....	1
Background.....	1
DESIGN AND METHODOLOGY.....	6
RESULTS AND DISCUSSION.....	17
CONCLUSION.....	39
APPENDIX A: FDA FOODBORNE ILLNESS RISK FACTOR STUDY DATA COLLECTION FORM.....	42
APPENDIX B: DATA COLLECTION INTRODUCTION LETTER.....	60
APPENDIX C: LIMITATIONS.....	62
APPENDIX D: DATA COLLECTION CYCLE FOR THE RESTAURANT INDUSTRY ...	66
APPENDIX E: SUPPLEMENTAL STATISTICAL ANALYSIS.....	67
ACRONYMS/ABBREVIATIONS.....	74
REFERENCES.....	75

LIST OF TABLES

Table 1	Summary of Data Collection Time Frames for the Restaurant Industry	3
Table 2	Description of Restaurant Facility Types Included in the Study	6
Table 3	Risk Categorization of Food Establishments	7
Table 4	Foodborne Illness Risk Factors and the Associated Primary Data Items Examined in the Study	11
Table 5	Descriptive Statistics.....	19
Table 6	Jurisdictional Characteristics	20
Table 7	Total Number and Percentage of Restaurants Out-of-compliance for Each Risk Factor	21
Table 8	Total Number and Percentage of Restaurants Out-of-compliance for Each Data Item.....	22
Table 9	Primary Data Items Out-of-compliance in Descending Order of Percentage	23
Table 10	Overall Number of Primary Data Items Out-of-compliance Percentiles (Fast Food Restaurants).....	25
Table 11	Overall Number of Primary Data Items Out-of-compliance Percentiles (Full- service Restaurants)	26
Table 12	Mean Number of Primary Data Items Out-of-compliance by Multiple- unit Operation Status (Fast Food Restaurants).....	27
Table 13	Mean Number of Primary Data Items Out-of-compliance by Risk Category (Fast Food Restaurants)	27
Table 14	Mean Number of Primary Data Items Out-of-compliance by Jurisdiction Variable (Fast Food Restaurants)	28
Table 15	Mean Number of Primary Data Items Out-of-compliance by Certified Food Protection Manager Status (Fast Food Restaurants)	29
Table 16	Mean Number of Primary Data Items Out-of-compliance by Multiple- unit Operation Status (Full-service Restaurants)	29
Table 17	Mean Number of Primary Data Items Out-of-compliance by Risk Category (Full-service Restaurants)	30
Table 18	Mean Number of Primary Data Items Out-of-compliance by Jurisdiction Variables (Full-service Restaurants)	30
Table 19	Mean Number of Primary Data Items Out-of-compliance by Certified Food Protection Manager Status (Full-service Restaurants).....	31
Table 20	Pearson Product Correlations between Study Variables (Fast Food Restaurants).....	33
Table 21	Pearson Product Correlations between Study Variables (Full-service Restaurants).....	34
Table 22	Tests for Predictors of Out-Of-Compliance Items for Fast Food Restaurants	35

Table 23 Regression Analysis (Fast Food Restaurants)	36
Table 24 Least Squares Means (Fast Food Restaurants)	36
Table 25 Tests for Predictors of Out-Of-Compliance Items for Full-service Restaurants	37
Table 26 Regression Analysis (Full-service Restaurants)	38
Table 27 Least Squares means (Full-service Restaurants).....	38
Table 28 Summary of Data Collection Time Frames for the Restaurant Industry.....	66
Table 29 Fast Food Restaurants multi-factor ANOVA.....	68
Table 30 Full-service restaurants multi-factor ANOVA.....	69
Table 31 ANOVA by Food Safety Management System: Full-service Restaurant	73
Table 32 ANOVA by Food Safety Management System: Fast Food Restaurant	73
Table 33 Acronyms and Abbreviations	74

LIST OF FIGURES

Figure 1	Study Selection Areas within a 150-mile Radius from 22 Specialists' Locations	8
Figure 2	Bubble Plot of Mean Out of Compliance by Food Safety Management System	71

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 restaurant settings during 2013-2014. It is a stand-alone report representing the first data collection period of the FDA's current 10-year study on trends in the occurrence of foodborne illness risk factors, food safety behaviors/practices, and interventions in food service facilities. Data from the 2013-2014 collection will be used as a baseline to assess trends in the occurrence of risk factors during data collections, in 2017 and 2021. Additional data collections in 2015, 2019, and 2023 investigate similar retail food safety research questions in institutional food service settings and retail food stores.

BACKGROUND

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, Nguyen, & Han, 2012; Stewart, Blisard, Bhuyan, & Nayga Jr., 2004), with more than one million restaurant locations employing more than 14 million people (NRA, 2016). 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.

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 77.7 billion dollars (Scharff, 2012).

According to the Centers for Disease Control and Prevention (CDC, 2014) more than half of foodborne illness outbreaks that occur each year are associated with food from restaurants. When considering incidents in 2014 involving a single location of food preparation, for example, restaurants accounted for 485 outbreaks (65%) and 4,780 illnesses (44%) (CDC, 2014).

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, with a median of 620 outbreaks per year. Norovirus caused 46% of the 3,072 outbreaks associated with a single, confirmed etiology. Activities related to food handling and preparation practices were the most commonly reported contributing factors within restaurant-associated outbreaks.

Surveillance data from the CDC have 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. 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 these risk factors and their respective intervention strategies provides a consistent means of monitoring food safety efforts and determining trends over time within the restaurant industry. The U.S. Food and Drug Administration (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.

FDA previously conducted a 10-year study between 1998-2008 to measure trends in the occurrence of foodborne illness risk factors and food safety behaviors/practices. This study consisted of three data collection periods (1998, 2003, and 2008), and FDA summarized the findings for each (FDA, 2000; FDA, 2004; FDA, 2009). Data from all three periods were analyzed to detect trends over time and determine whether progress had been made toward the goal of reducing the occurrence of risk factors in food service and retail food establishments (FDA, 2010). Significant improvement in at least one risk factor occurred in eight of the nine facility types FDA studied; however, many segments of the retail food industry continued to require improvement in three critical areas:

- Poor personal hygiene
- Improper food holding/time and temperature
- Contaminated equipment/protection from contamination

At the conclusion of the 10-year study conducted between 1998 and 2008, FDA determined that it needed additional research to identify the root causes for all poor retail food safety practices and to determine the most effective intervention strategies

and inspection approaches for enhancing the safety of the nation’s retail food protection system.

The 2013-2014 data collection reported here starts the process of additional research. The intervention strategies and factors of interest encompass active managerial control, regulatory characteristics, and establishment characteristics. Data from the 2013-2014 collection will be used as a baseline to assess trends in the occurrence of risk factors during data collections, in 2017 and 2021. Table 1 summarizes the time frames for restaurant data collection within the overall study period.

Table 1 Summary of Data Collection Time Frames for the Restaurant Industry

Industry Segment	Facility Type	Initial Data Collection Period (Baseline Measurement)	2 ND Data Collection Period	3 RD Data Collection Period
Restaurants	Full-service Restaurants and Fast Food Restaurants	Nov. 15, 2013 to Sept. 30, 2014	Oct. 1, 2017 to Sept. 30, 2018	Oct. 1, 2021 to Sept. 30, 2022

Purpose of the Study

The purpose of each restaurant data collection during the current 10-year study period is to investigate the relationship between food safety management systems (FSMS), certified food protection managers (CFPMs), and the occurrence of risk factors and food safety behaviors/practices commonly associated with foodborne illness in restaurants.

FSMS refers to a specific set of actions (e.g., procedures, training, and monitoring) to help achieve active managerial control. While FSMS procedures vary across the retail and food service industry, purposeful implementation of those procedures, training, and monitoring are consistent components of FSMS. While several systems and tools are available internationally, including International Organization for Standardization (ISO 22000), Good Manufacturing Practices (GMP), Hazard Analysis and Critical Control Points (HACCP), British Retail Consortium (BRC) and Safe Quality Food Institute (SQF) (Codex, 2003; ISO 22000:2005, 2005; Luning et al., 2008), the ongoing prevalence and degree of implementation of these or similar systems within restaurants 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, but the poor implementation of HACCP has been described as a precursor to foodborne outbreaks (Cormier, 2007; Luning et al., 2009; Ropkins and 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 inspection scores (Hedberg et al., 2007; Cates et al., 2008, Brown et al., 2014). Hedberg et al. (2006) found that the major difference between outbreak and non-outbreak restaurants was the presence of a CFPM.

Our objectives are to:

- Identify the least and most often occurring foodborne illness risk factor and food safety behaviors/practices in restaurants within the United States
- Determine the extent to which FSMS and the presence of a CFPM impact the occurrence of food safety behaviors/practices
- Determine whether the occurrence of food safety behaviors/practices in restaurants 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 units)

The results of the current 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

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 active managerial control (AMC) of the risk factors contributing to foodborne illness in retail and food service facilities. AMC is “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” (FDA, 2013). A food establishment’s 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 a CFPM and FSMS.

Regulatory Authority Characteristics

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

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. 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 (Table 2).

Table 2 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 Regional Retail Food Specialists (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 3). 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 3 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 active managerial control 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 active managerial control of foodborne illness risk factors is achieved and documented.
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 active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of active managerial control 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

Twenty-two specialists conducted site visits throughout the United States at randomly selected restaurants to perform data collections. All specialists received customized training specific to the study data collection protocol and marking instructions for the standardized data collection tool. FDA's Center for Food Safety and Applied Nutrition (CFSAN) personnel standardized the specialists in applying and interpreting the FDA *Food Code*. In addition, all specialists 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 as the establishment inventory for the restaurant data collection. The total number of establishments in the country was approximately 472,243. Restaurants were randomly selected to participate in the study from among all eligible establishments located within a 150-mile radius of the home locations of the twenty-two specialists who conducted the data collections at restaurants. The total number of establishments within the sampling zones was 295,003. As a result, roughly 62% of all establishments in the restaurant segment were eligible for selection. Figure 1 depicts the sample selection coverage area.

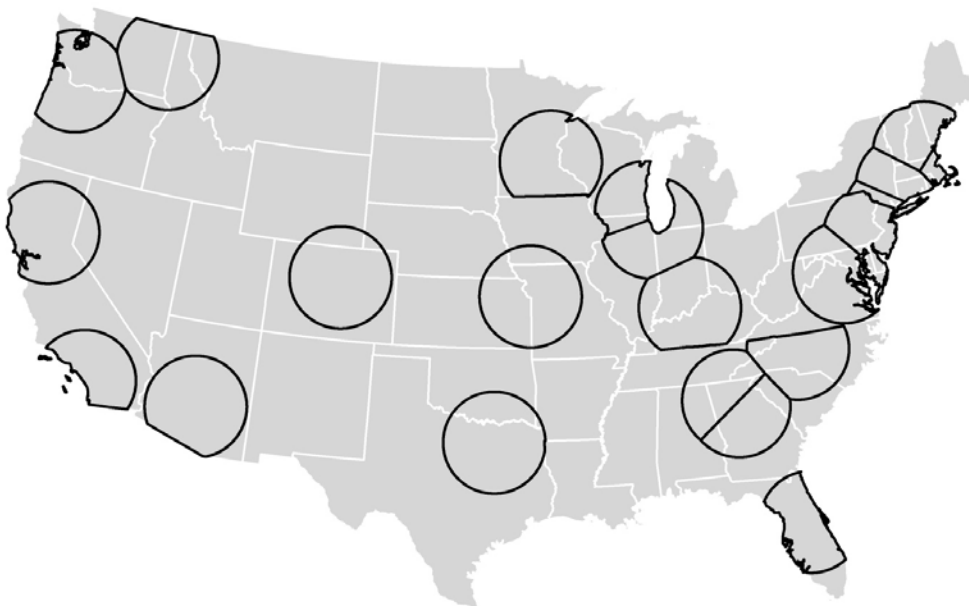


Figure 1 Study Selection Areas within a 150-mile Radius from 22 Specialists' Locations

Sample Size

The FDA 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 396 data collections for full-service restaurants and 425 for fast food restaurants.

The sample establishment inventory was distributed evenly among the specialists. Since industry participation in the study was voluntary, a list of substitute restaurants was selected for each specialist for establishments that were found to be misclassified, closed, or otherwise unable or unwilling to participate. The FDA 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 (2013-2023) – 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. Specialists verified that the selected restaurant was placed in the proper restaurant category and, through discussions with the regulatory authority, determined whether the restaurant was under any legal notice. If the selected restaurant was under a legal notice, closed, or misclassified, the specialist 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 specialist obtained information pertaining to its retail food inspection program, such as enrollment in the FDA Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), timing 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 and provided 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 specialist 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 specialist during the data collection and conditions warranted regulatory action, the specialist contacted the regulatory authority after completing the data collection so that any necessary follow up could occur.

Data Collection Protocol

The specialist conducted unannounced, non-regulatory visits to each selected restaurant. Upon arrival at the establishment, the specialist explained the purpose of the visit to the owner or person in charge. An introductory letter explaining the purpose of the data collection visit, included in Appendix B, was also presented to the person in charge. If the owner or person in charge denied entry into the 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 specialist used the 2013 FDA *Food Code* 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 clear understanding of food processes and procedures. The owner or person in charge of the restaurant was encouraged to accompany the specialist during data collection.

Risk Factors and Associated Data Items

This study focuses 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 (data items), were used as the key indicators for FDA's statistical analysis for this study. Data items in this study are based on FDA *Food Code* recommendations and are designed to control food safety behaviors/practices. Table 4 presents the 10 data items and their associated risk factors. Ensuring that food is obtained from an approved source is the first line of defense for restaurants. FDA's study design did not include this risk factor under the primary data items because the agency observed low out-of-compliance

percentages in the previous FDA 10-year study, and inspections conducted by regulatory partners substantiated these findings.

Table 4 Foodborne Illness Risk Factors and the Associated Primary Data Items Examined in the Study

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

Data Items, Information Statements, and Documenting Observations

Using the 2013 version of the FDA *Food Code*, the specialist marked observations and findings on the data collection form in four categories (see Appendix A). The specialist determined whether observations of employee food safety practices or behaviors contained in the information statements were in compliance, out-of-compliance, not observed, or not applicable:

- **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 specialist 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.¹ The following formula calculates the percentage of out-of-compliance observations for each data item:

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

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 shows 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 eight out of 10 establishments where cooling of TCS foods was observed. The 80% score should not be interpreted to mean that foods were not cooled properly 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:

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

¹ The previous FDA *Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types* (2009) used a weighted average.

Assessing Food Protection Manager Certification

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

- A CFPM was employed at the restaurant
- A CFPM was present during data collection
- The person in charge (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 specialist made an attempt to verify the response by requesting to view a copy of the certificate. The specialist also noted whether the certification was obtained from

- An American National Standards Institute (ANSI)-accredited food protection manager certification program².
- 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 restaurant
- A source for which the restaurant personnel could not provide documentation or specific reference

In addition, by interviewing the person in charge, the specialist determined whether it was the restaurant’s policy to have a food protection manager present at all times, to gather baseline information on restaurants that have such a policy in place.

Assessing Food Safety Management Systems

A FSMS refers to a specific set of actions and/or procedures to help achieve active managerial control. While FSMS vary across the retail and food service industry, the purposeful implementation of those procedures, training, and monitoring are consistent components of FSMS. For the purpose of this study, these three key elements were used to assess a restaurant’s FSMS:

² 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 restaurant 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. During data collection, the specialist assessed each restaurant's FSMS to determine the extent to which FSMS were developed and implemented in the restaurant to control one of the four foodborne illness risk factors shown in Table 4 that include the 10 primary data items in the study. The risk factor for which a FSMS assessment was conducted in each restaurant was randomly selected.

For each of three FSMS key elements, the specialist interviewed the person in charge 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 specialist used a standardized system to rate each food safety management system element (Procedures, Training, and Monitoring (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.

This 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.

This 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) or analyzed as a categorical variable with a score of 1 being nonexistent, scores higher than 1 but less than 3 categorized as underdeveloped, scores of 3 but less than 4 categorized as well-developed, and scores of 4 categorized as well-developed and documented.

To illustrate, if the poor personal hygiene risk factor was selected as the area for the specialist 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 ready-to-eat 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 restaurant 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 by each specialist 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 were 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

Before conducting a statistical review of the data, the responses to each data item, along with corresponding comments entered by the specialist, were reviewed by a team including FDA staff from both the Office of Regulatory Affairs (ORA) and CFSAN to ensure consistency with the study marking instructions for the data collection form.

Statistical Analysis

Statistical analysis of the data was performed utilizing JMP®, Version 12. Statistical significance of individual variables was determined at $p < 0.05$ to understand the relative effect of each variable on the out-of-compliance of data items. The data were 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

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.

Results are presented in five parts:

- Descriptive statistics
- Occurrence of risk factors and out-of-compliance data items
- Regulatory and establishment characteristics and the occurrence of out-of-compliance data items
- Correlations
- Regression

Descriptive Statistics

This study included 425 fast food restaurants and 396 full-service restaurants:

- Risk category and status as a multiple-unit operation differed between fast food and full-service restaurants. Seventy percent of fast food restaurants were risk category 2, whereas 87% of full-service restaurants were risk category 3.
- The majority of fast food restaurants (79%) were part of a multiple-unit operation, whereas the majority of full-service operations (63%) were not.
- Thirty-nine percent of fast food restaurants had well-developed and well-developed and documented FSMS, as opposed to only 9% of full-service restaurants.
- In fast food restaurants that were part of multiple-unit operations, 48.5% of establishments had well-developed or well-developed and documented FSMS, as compared to only 1.1% of single-unit establishments. Full-service restaurants had values of 20.3% and 2.0%, respectively.

Table 5 shows the distribution of the establishments in the study based on the certified food protection manager status. The important take away is that most of the establishments had a CFPM in charge at the time of data collection. Table 5 does not address the question of whether the CFPM is always present, only the conditions observed during the data collection. Sixty-four percent of fast food restaurants had a person in charge who was a CFPM and present at the time of data collection, whereas

19% had no CFPM at all. In full-service restaurants, 58% had a person in charge who was a CFPM and present at the time of data collection, as opposed to 26% with no CFPM. It is worth noting that the majority of all restaurants in this study operated in jurisdictions enrolled in the VNRFRPS, 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).³ 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).

³ The VNRFRPS (Voluntary National Retail Food Regulatory Program Standards) define what constitutes a highly effective and responsive program for regulating food service and retail food establishments. They begin by providing a regulatory foundation (Program Standard 1), which includes any statute, regulation, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment. They progress to a system upon which all regulatory programs can build through a continuous improvement process. The Retail Program Standards encourage regulatory agencies to improve and build upon existing programs. Further, they provide a framework designed to accommodate both traditional and emerging approaches to food safety. More information is available at <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ProgramStandards/default.htm>.

Table 5 Descriptive Statistics

Characteristic	Number of Fast Food Restaurants (N = 425)	%	Number of Full-service Restaurants (N = 396)	%
Certified Food Protection Manager				
<i>None</i>	82	19.29	101	25.51
<i>Employed but not present</i>	53	12.47	45	11.36
<i>Employed and present</i>	16	3.76	20	5.05
<i>Person in charge</i>	274	64.47	230	58.08
Food Safety Management System⁴				
<i>Nonexistent</i>	56	13.37	124	31.31
<i>Underdeveloped</i>	201	47.97	237	59.85
<i>Well-developed</i>	119	28.40	24	6.06
<i>Well-developed and documented</i>	43	10.26	11	2.78
Risk Categorization				
<i>Risk category 2</i>	298	70.12	35	8.84
<i>Risk category 3</i>	126	29.65	343	86.62
<i>Risk category 4</i>	1	0.24	18	4.55
Multiple-unit				
<i>Yes</i>	337	79.29	148	37.37
<i>No</i>	88	20.71	248	62.63

⁴ PTM evaluations were not performed for six establishments at which inadequate cooking was randomly selected as the area for the specialist to conduct a FSMS assessment. A FSMS assessment of the inadequate cooking risk factor required calculation of an overall PTM score based on an evaluation of data items 9 (Raw animal foods are cooked to required temperatures) and 10 (Cooked foods are reheated to required temperatures). However, the six establishments did not do any cooking or reheating so data items 9 and 10 were marked not applicable.

Table 6 Jurisdictional Characteristics

Characteristic	Number of Fast Food Restaurants (N = 425)	%	Number of Full-service Restaurants (N = 396)	%
Jurisdiction enrolled in VNRFRPS				
Yes	283	66.59	244	61.62
No	142	33.41	152	38.38
Jurisdiction meets VNRFRPS Standard 1				
Yes	98	34.63	80	32.79
No	185	65.37	164	67.21
Jurisdiction uses a grading system				
Yes	264	62.12	225	56.82
No	161	37.88	171	43.18
Jurisdiction requires public posting of inspection results				
Yes	324	76.24	286	72.22
No	101	23.76	110	27.78
Jurisdiction has mandatory certified food protection manager requirement				
Yes	299	70.35	279	70.45
No	126	29.65	117	29.55

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 821 restaurants (425 fast food and 396 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/Time and Temperature (fast food, 78%; full-service restaurants, 95%) and poor personal hygiene (fast food, 67%; full-service restaurants, 83%). Inadequate cooking was the least commonly occurring risk factor found out-of-compliance in both fast food (15%) and full-service restaurants (33%). This risk factor (inadequate cooking) was only observed in 65% of fast food restaurants (277/425) and in 82% of full-service restaurants (323/396). 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 (see Appendix C).

Table 7 Total Number and Percentage of Restaurants Out-of-compliance for Each Risk Factor

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	283	425	66.59	329	396	83.08
Contaminated Equipment	242	425	56.94	325	396	82.07
Improper Holding/Time and Temperature	330	425	77.65	375	396	94.70
Inadequate Cooking	42	277	15.16	105	323	32.51

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.

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	277	422	65.64	323	392	82.40
2	Employees do not contact ready-to-eat foods with bare hands	53	425	12.47	133	396	33.59
3	Food is protected from cross contamination during storage, preparation, and display	157	425	36.94	265	396	66.92
4	Food contact surfaces are properly cleaned and sanitized	174	425	40.94	246	396	62.12
5	Foods requiring refrigeration are held at proper temperature	290	425	68.24	341	396	86.11
6	Foods displayed or stored hot are held at proper temperature	80	334	23.95	116	334	34.73
7	Foods are cooled properly	85	172	49.42	196	273	71.79
8	Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening	129	402	32.09	272	385	70.65
9	Raw animal foods are cooked to required temperatures	23	216	10.65	64	304	21.05
10	Cooked foods are reheated to required temperatures	21	131	16.03	48	131	36.64

Table 9 lists in (descending order) out-of-compliance percentages for each primary data item.

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	68.24	5	Foods requiring refrigeration are held at proper temperature	86.11
1	Employees practice proper handwashing	65.64	1	Employees practice proper handwashing	82.40
7	Foods are cooled properly	49.42	7	Foods are cooled properly	71.79
4	Food contact surfaces are properly cleaned and sanitized	40.94	8	Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening	70.65
3	Food is protected from cross contamination during storage, preparation, and display	36.94	3	Food is protected from cross contamination during storage, preparation, and display	66.92
8	Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening	32.09	4	Food contact surfaces are properly cleaned and sanitized	62.12
6	Foods displayed or stored hot are held at proper temperature	23.95	10	Cooked foods are reheated to required temperatures	36.64
10	Cooked foods are reheated to required temperatures	16.03	6	Foods displayed or stored hot are held at proper temperature	34.73
2	Employees do not contact ready-to-eat foods with bare hands	12.47	2	Employees do not contact ready-to-eat foods with bare hands	33.59
9	Raw animal foods are cooked to required temperatures	10.65	9	Raw animal foods are cooked to required temperatures	21.05

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 over the same two data items (2,9) and also had the least control over the same two data items (5,1). When a data item or risk factor is IN compliance then the facility has control over that data item or risk factor. The data items or risk factors with the lower OUT of compliance percentages indicate more control over the data item or

risk factor. In this study both fast food and full-service restaurants have the most control over data item 9 since it has the lowest OUT of compliance percentage.

Data item 2 (employees do not contact ready-to-eat foods with bare hands) and Data item 9 (raw animal foods are cooked to required temperatures) were found out-of-compliance least commonly at 12% and 11%, respectively, for fast food restaurants, and 34% and 21%, respectively, for full-service restaurants. Data item 5 (foods requiring refrigeration are held at proper temperature) and Data item 1 (employees practice proper handwashing) were found out-of-compliance most commonly at 68% and 66%, respectively, for fast food restaurants, and 86% and 82%, respectively, for full-service restaurants. This suggests that while restaurants are better at managing bare-hand contact with ready-to-eat foods and ensuring foods are cooked to required temperatures, there remains a need to gain better control over cold holding foods requiring refrigeration and employee handwashing.

The high out-of-compliance percentage of the improper holding risk factor (Table 7) in fast food restaurants (78%) was largely due to high out-of-compliance findings in two of the four data items the risk factor includes: Data item 5 (foods requiring refrigeration are held at proper temperature) and Data item 7 (foods are cooled properly). These data items had out-of-compliance percentages of 68% and 49%, respectively, as shown in Table 9.

The high out-of-compliance percentage of the improper holding risk factor (Table 7) in full-service restaurants (95%) was largely due to high out-of-compliance findings in three of the four data items that the risk factor includes: Data item 5 (foods requiring refrigeration are held at proper temperature), Data item 7 (foods are cooled properly), and Data item 8 (refrigerated, ready-to-eat foods are properly date marked and discarded within seven days of preparation or opening). These data items had out-of-compliance percentages of 86%, 72%, and 71%, respectively, as shown in Table 9.

The out-of-compliance finding with handwashing (data item 1; 66%) in fast food restaurants (Table 8) was due to at least one observation in 57% of fast food restaurants that an employee did not clean and wash their hands at the required time, and in 45% 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; 82%) in full-service restaurants (Table 8) was due to at least one observation in 80% of full-service restaurants that an employee did not clean and wash their hands at the required times, and in 61% of full-service restaurants that at least one employee was not properly cleaning and washing their hands.

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
- 63% (269) had 3 or fewer primary data items out-of-compliance
- 8% (36) had no primary data items out-of-compliance
- 15% (63) had one primary data item out-of-compliance

Full-service Restaurants

- Median number of primary data items out-of-compliance = 5
- 55% (217) had 5 or fewer primary data items out-of-compliance
- 2% (8) had no primary data items out-of-compliance
- 3% (13) had one primary data item out-of-compliance

Table 10 Overall Number of Primary Data Items Out-of-compliance Percentiles (Fast Food Restaurants)

Number of Primary Data Items Out-of-compliance	Number of Fast Food Restaurants	%	Cumulative Number of Fast Food Restaurants	Cumulative %
0	36	8.47	36	8.47
1	63	14.82	99	23.29
2	84	19.76	183	43.06
3	86	20.24	269	63.29
4	58	13.65	327	76.94
5	48	11.29	375	88.24
6	28	6.59	403	94.82
7	16	3.76	419	98.59
8	6	1.41	425	100.00
9	0	0.00	425	100.00
10	0	0.00	425	100.00

**Table 11 Overall 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	2.02	8	2.02
1	13	3.28	21	5.30
2	29	7.32	50	12.63
3	33	8.33	83	20.96
4	55	13.89	138	34.85
5	79	19.95	217	54.80
6	86	21.72	303	76.52
7	47	11.87	350	88.38
8	41	10.35	391	98.74
9	4	1.01	395	99.75
10	1	0.25	396	100.00

Regulatory and Establishment Characteristics and the Occurrence of Out-of-compliance Data Items

Fast Food Restaurants

A. 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 ($p < 0.01$) compared to those not part of a multiple-unit operation (Table 12). Restaurants part of an operation with two or more units were classified as multiple-unit operations.

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	88	4.51
Yes	337	2.65

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). Statistical comparisons were not performed on one fast food restaurant designated as risk category 4.

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	298	2.86
3	126	3.42

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 ($p = 0.5573$) 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 ($p = 0.8440$) than those without inspection reporting. Establishments in jurisdictions that required food handler training did not have significantly different compliance ($p = 0.8448$) 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	161	2.96
Yes	264	3.08
Inspection Reporting		
No	101	3.00
Yes	324	3.04
Food Handler Training Requirement		
No	266	3.02
Yes	159	3.06

D. Certified Food Protection Managers

As indicated in Table 15, fast food restaurants with no CFPM employed at the restaurant averaged 3.4634 primary data items out-of-compliance. Those with a CFPM employed at the restaurant but not present during data collection had an average of 3.2642 primary data items out-of-compliance. The difference is not significant ($p = 0.5620$). Those establishments with a CFPM present at the time of data collection had an average of 2.6875 primary data items out-of-compliance. The average number out-of-compliance was not significantly different from those establishments with no CFPM employed ($p = 0.1278$). Fast food restaurants with a CFPM present and in charge had a significantly lower number of data items out-of-compliance than those with no CFPM ($p = 0.0160$). This indicates a significant difference in the number of out-of-compliance data items between establishments with a CFPM present and those that did not have a CFPM present at the time of data collection.

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	82	3.46
Yes	No	No	53	3.26
Yes	Yes	No	16	2.69
Yes	Yes	Yes	274	2.88

Full-service Restaurants

A. 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 ($p < 0.01$) compared to those not part of a multiple-unit operation (Table 16). Restaurants part of an operation with two or more units were classified as multiple-unit operations.

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	248	5.30
Yes	148	4.66

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 18 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	35	4.20
3	353	5.14

C. Grading, Inspection Reporting, and Food Handler Training

Full-service restaurants located in jurisdictions that graded establishments did not have significantly different results ($p = 0.0819$) 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 ($p = 0.6820$) than establishments in jurisdictions that did not require reporting. Establishments in jurisdictions that required food handler training did not have significantly different compliance ($p = 0.0626$) 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	171	4.86
Yes	225	5.21
Inspection Reporting		
No	110	3.00
Yes	286	3.04
Food Handler Training		
No	262	5.19
Yes	134	4.80

D. Certified Food Protection Managers

As shown in Table 19, full-service restaurants with no CFPM employed averaged 5.6931 primary data items out-of-compliance. Those with a CFPM employed at the restaurant but not present during the data collection had an average of 5.4000 primary data items out-of-compliance. The difference is not statistically significant ($p = 0.3222$). Those establishments with a CFPM present at the time of data collection had an average of 4.8500 primary data items out-of-compliance. The average number out-of-compliance was significantly different from those establishments with no CFPM employed ($p = 0.0343$). Full-service restaurants with a CFPM present and in charge had a significantly lower number of data items out-of-compliance than those with no CFPM ($p < 0.0001$). This indicates a significant difference in the number of out-of-compliance data items between establishments with a CFPM present and those without a CFPM present at the time of data collection.

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	101	5.69
Yes	No	No	45	5.40
Yes	Yes	No	20	4.85
Yes	Yes	Yes	230	4.73

Correlations

Tables 20 and 21 present Pearson's product moment correlations between different factors. Pearson's product moment correlations appearing with an asterisk are significant ($p < 0.05$). The Spearman correlation is also presented for selected pairs.

Spearman's rank-order coefficient is the nonparametric version of Pearson's coefficient and was used as a second measure to evaluate correlation. Pearson's coefficient assesses linearity, whereas Spearman's coefficient assesses monotonicity (including nonlinear relationships).

The CFPM variable was converted to an ordinal variable for the correlation analysis. Having no CFPM employed was coded as 1, having a CFPM employed but not present was coded as 2, having a CFPM present was coded as 3, and having the CFPM in charge was coded as 4.

In fast food restaurants, food safety management systems were highly correlated with a CFPM, multiple-unit operations, and the number of primary data items out-of-compliance. The positive correlation 0.3157 (Spearman's $\rho = 0.3081$, $p < 0.01$) indicates that as the certified food protection manager category increases, the food safety management systems category also increases. Multiple-unit operations were correlated, 0.5633, (Spearman's $\rho = 0.5625$, $p < 0.01$) with better food safety management systems. This indicates that multiple-unit operations tended to have better FSMS. FSMS were negatively correlated with the number of primary data items out-of-compliance, -0.4205, (Spearman's $\rho = -0.4125$, $p < 0.01$). This negative correlation indicates that as the FSMS category increases, the number of primary data items out-of-compliance decreases. Multiple-unit operations are also correlated with the number of primary data items out-of-compliance, -0.3934, (Spearman's $\rho = -0.3725$, $p < 0.01$). This indicates that multiple-unit operations are correlated with lower numbers of primary data items out-of-compliance.

In full-service restaurants, food safety management systems were correlated with a CFPM (0.2882), multiple-unit operations (0.4592), and number of primary data items out-of-compliance (-0.4549) (Spearman's $\rho = 0.2509$, 0.4226, and -0.4102, respectively; $p < 0.01$ for each). As the CFPM category increases, the FSMS category also increases. Multiple-unit operations were positively correlated with FSMS. FSMS were negatively correlated with the number of primary data items out-of-compliance, indicating an inverse relationship. Increases in the FSMS category were correlated with lower numbers of primary data items out-of-compliance.

Table 20 Pearson Product Correlations between Study Variables (Fast Food Restaurants)

Variable	1	2	3	4	5	6	7	8	9	10
1. CFPM	1.0000									
2. FSMS	0.3157*	1.0000								
3. Risk Category	-0.0706	-0.1596*	1.0000							
4. Multiple-unit Status	0.1402*	0.5633*	-0.2190*	1.0000						
5. Inspection Reporting	0.0114	0.0699	-0.0784	0.0012	1.0000					
6. Enrollment in VNRFRPS	-0.0483	0.2145*	0.0513	0.0935	0.2960*	1.0000				
7. Grading	-0.0574	-0.1359*	0.0994*	-0.0798	-0.2819*	-0.0844	1.0000			
8. Mandatory CFPM	0.3628*	-0.0093	-0.1005*	-0.1156*	-0.1567*	-0.2086*	0.0396	1.0000		
9. Number of Data Items Out-of-compliance	-0.1240*	-0.4205*	0.1394*	-0.3934*	0.0096	-0.1203*	-0.0285	0.0648	1.0000	
10. Number of Risk Factors	-0.1247*	-0.3020*	0.0633	-0.2329*	0.0600	-0.0596	-0.0651	0.0247	0.8532*	1.0000

*p < 0.05, CFPM – Certified Food Protection Manager, FSMS – Food Safety Management System, VNRFRPS – Voluntary National Retail Food Regulatory Program Standards.

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

Variable	1	2	3	4	5	6	7	8	9	10
1. CFPM	1.0000									
2. FSMS	0.2882*	1.0000								
3. Risk Category	0.0545	-0.0237	1.0000							
4. Multiple-unit Status	0.1370*	0.4592*	-0.1099*	1.0000						
5. Inspection Reporting	-0.0548	0.1117*	-0.0422	0.1528*	1.0000					
6. Enrollment in VNRFRPS	-0.1608*	0.1102*	-0.0075	0.0838	0.3684*	1.0000				
7. Grading	0.0169	-0.0770	-0.0092	-0.1676*	-0.2789*	-0.1296*	1.0000			
8. Mandatory CFPM	0.6089*	0.0848	-0.0003	0.0426	-0.1545*	-0.2607*	0.0282	1.0000		
9. Number of Data Items Out-of-compliance	-0.2101*	-0.4549*	0.1147*	-0.1538*	-0.0207	0.0680	-0.0875	-0.0772	1.0000	
10. Number of Risk Factors	-0.1420*	-0.2909*	0.0690	-0.0347	-0.0064	0.0729	-0.1264*	-0.0314	0.7970*	1.0000

*p < 0.05 CFPM – Certified Food Protection Manager, FSMS – Food Safety Management System, VNRFRPS – Voluntary National Retail Food Regulatory Program Standards.

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. The explanatory variables most highly correlated with the response are discussed below.

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 ($F(6,412) = 18.956, p < 0.01$). 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 Tests for Predictors of Out-Of-Compliance Items for Fast Food Restaurants

Variable	Number of Parameters	Degrees of Freedom (df)	Sum of Squares	F Ratio	P-value
Risk Category	1	1	4.16	1.42	0.2344
Multiple-unit	1	1	48.10	16.38	<0.0001*
CFPM	3	3	0.67	0.08	0.9730
FSMS	1	1	80.48	27.41	<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=Person in charge
 FSMS treated as continuous variable, possible values from 1-4.

Table 23 presents the results of the regression analysis. Risk category was not a significant predictor of out-of-compliance data items in fast food restaurants ($B = 0.2214, t(1) = 1.19, p = 0.2344$). Multiple-unit status ($b = 0.514, t(1) = 4.05, p < 0.01$) and FSMS ($B = -0.566, t(1) = -5.24, p < 0.01$) were found to be significant predictors 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 0.566 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 Restaurants)

Predicting Variable	<i>B</i>	Standard Error	<i>t</i>	<i>p</i>
Risk Category	0.22	0.19	1.19	0.2344
Multiple-unit: No	0.51	0.13	4.05	<0.0001*
CFPM: Employed	0.08	0.21	0.39	0.6984
CFPM: None	0.02	0.20	0.08	0.9381
CFPM: Person in Charge	0.04	0.15	0.28	0.7811
FSMS	-0.57	0.11	-5.24	<0.0001*

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

The multiple-unit effect can be seen when the least squares means are analyzed (Table 24). There was a significant difference ($p < 0.05$) in the number of primary data items out-of-compliance depending upon the restaurant’s status as a multiple-unit operation. The least squares means were not significantly different for any level of CFPM (Table 24).

Table 24 Least Squares Means (Fast Food Restaurants)

Variable	Least Squares Means	Standard Error
Multiple-unit		
<i>No</i>	3.83	0.24
<i>Yes</i>	2.81	0.14
CFPM		
<i>None</i>	3.33	0.22
<i>Employed</i>	3.40	0.25
<i>Person in charge</i>	3.36	0.13
<i>Present</i>	3.18	0.43

CFPM – Certified Food Protection Manager

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 ($F(6,389) = 61.1948, p < 0.01$). Table 25 presents the results of the effects tests, which tests the null hypothesis that all parameters associated with the effect are zero.

Table 25 Tests for Predictors of Out-Of-Compliance Items for Full-service Restaurants

Variable	Number of Parameters	Degrees of Freedom (df)	Sum of Squares	F Ratio	Prob > F
Risk Category	1	1	21.61	6.89	0.0090*
Multiple-unit	1	1	8.99	2.87	0.0911
CFPM	3	3	12.96	1.38	0.2492
FSMS	1	1	250.34	79.86	<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=Person in charge
FSMS treated as continuous variable, possible values from 1-4.

Table 26 presents the results of the regression analysis. Risk category ($B = 0.652, t(1) = 2.63, p < 0.01$) and FSMS ($B = -1.207, t(1) = -8.94, p < 0.01$) 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 1.207095 in the number of primary data items out-of-compliance. Risk category is positive, indicating that as risk category increases, the number of primary data items out-of-compliance increases by 0.6527986. Multiple-unit status ($B = -0.176, t(1) = -1.69, p = 0.091$) and CFPM were not significant predictors of out-of-compliance data items (Table 26).

Table 26 Regression Analysis (Full-service Restaurants)

Predicting Variable	<i>B</i>	Standard Error	<i>t</i>	<i>p</i>
Risk Category	0.65	0.25	2.63	0.0090*
Multiple-unit: No	-0.18	0.10	-1.69	0.0911
CFPM: Employed	0.08	0.23	0.37	0.7130
CFPM: None	0.21	0.18	1.13	0.2607
CFPM: Person in Charge	-0.22	0.16	-1.43	0.1544
FSMS	-1.21	0.14	-8.94	<0.0001*

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

Table 27 presents least squares means for multiple-unit operations and CFPM. There are no significant differences in the least squares means between single-unit and multiple-unit operations or between the levels of CFPM.

Table 27 Least Squares means (Full-service Restaurants)

Variable	Least Squares Means	Standard Error
Multiple-unit		
<i>No</i>	5.00	0.15
<i>Yes</i>	5.35	0.19
CFPM		
<i>None</i>	5.38	0.18
<i>Employed</i>	5.26	0.27
<i>Person in charge</i>	4.95	0.12
<i>Present</i>	5.11	0.40

CFPM – Certified Food Protection Manager

CONCLUSION

The purpose of this first data collection during the current study period 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.

Our objectives were to:

- Identify the least and most often occurring foodborne illness risk factor and food safety behaviors/practices in restaurants within the United States;
- Determine the extent to which FSMS and the presence of a CFPM impact the occurrence of food safety behaviors/practices; and
- Determine whether the occurrence of food safety behaviors/practices in restaurants differs based on a restaurant's risk categorization and status as a single-unit or multiple-unit operation.

Data analyses in this report showed the following:

- More than 70% of the restaurants in this study operated in jurisdictions that required a CFPM and most restaurants were found to have a CFPM employed and present 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 ready-to-eat foods; and
 - 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); and
 - Cold holding of foods requiring refrigeration.
- FSMS were the strongest predictor of data items being out-of-compliance in both fast food and full-service restaurants: those with well-developed food safety management systems had significantly fewer food safety behaviors/practices out-of-compliance than did those with less developed food safety management systems.

For example, fast food restaurants with nonexistent FSMS averaged almost 4.5 data items out-of-compliance, while fast food restaurants with well-developed and documented FSMS averaged fewer than 1.7 data items out-of-compliance. For full-service restaurants, facilities with nonexistent FSMS averaged 5.8 data items out-of-compliance, while those with well-developed and documented FSMS averaged 2.1 data items out-of-compliance.

- Restaurants with a CFPM present at the time of data collection were associated with fewer out-of-compliance food safety behaviors/practices than those whose CFPM was not present, based upon univariate examination. In fact, having a CFPM who was not present was almost no different than having no CFPM at all for the out-of-compliance food safety behaviors/practices evaluated in this study. This suggests that simply having a CFPM employed by the restaurant without that individual being present does not materially improve the restaurant's compliance. However, upon multi-factor regression, the correlations between certified food protection manager and out-of-compliance become non-significant, indicating that food safety management systems 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 person in charge 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 person in charge at the time of data collection, the average FSMS score was 2.645, while the average score for fast food restaurants with no CFPM employed was 1.822. In full-service restaurants, scores were 1.842 and 1.348, respectively. This suggests that having a CFPM present at all hours of operation enhances food safety management systems and reduces 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 at retail food establishments provide the foundation for implementing risk-based interventions designed to have the greatest impact on enhancing public health protection. FDA will continue to collect and use these data and results from this study as a source of information to aid decision makers in reducing the occurrence of risk factors responsible for causing foodborne illness. Continued research is needed to identify the causes of poor food safety practices in restaurants and to determine cost-effective, evidence-based intervention strategies and inspection approaches for improving the nation's retail food protection system.

APPENDICES

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

INDUSTRY SEGMENT			
Food Safety Management System Risk Factor Category:			
Industry Segment: Restaurants		Facility Type (Select ONE):	
		<input type="checkbox"/> Fast Food Restaurant <input type="checkbox"/> Full Service Restaurant	
DATA COLLECTION INFORMATION			
Date:		Data Collector:	
Time In:	Time Out:	Total Time in Minutes:	
Risk Categorization (Select ONE of the following):			
<input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4			
ESTABLISHMENT INFORMATION			
Establishment Name:			
Street Address:			
City:	State:	Zip:	County:
Maximum Number of Employees Per Shift:		Number of Employees Present at Time of Visit:	
Activity level at the time of visit (Select ONE): <input type="checkbox"/> Light <input type="checkbox"/> Moderate <input type="checkbox"/> Heavy			
Average Number of Meals Per Day:		Seating Capacity:	
ESTABLISHMENTS THAT ARE PART OF MULTI-UNIT OPERATIONS			
Establishment is part of a Multi-Unit Operation: <input type="checkbox"/> YES <input type="checkbox"/> NO			
Number of Individual Units that are part of the Multi-Unit Operation (Enter the number of units provided by the person in charge):			

INFORMATION ON THE REGULATORY AUTHORITY

Name of Jurisdiction with Regulatory Oversight:

Enrolled in FDA Retail Food Program Standards: YES NO

Jurisdiction Meets Standard 1 (Select **ONE** of the following):

- YES – Self Reported
- YES – Verified by Audit
- NO – Jurisdiction does not meet Standard 1

Jurisdiction Uses a Grading System (Select **ONE** of the following):

- YES – Numerical Score
- YES – Letter Grade
- YES – Color Graphic
- YES – Numerical Score and Letter Grade
- YES – Numerical Score and Color Graphic
- YES – Letter Grade and Color Graphic
- YES – Numerical Score, Letter Grade, and Color Graphic
- YES – Other
- NO – Jurisdiction does not have a grading system

If “Other” describe:

Jurisdiction’s Program Includes Public Reporting of Inspection Results (Select **ONE** of the following):

- YES – Posting on-site
- YES – Posting on the Internet
- YES – Posting on-site and Posting on the Internet
- YES – Other
- NO – Jurisdiction does not require inspections to be publically reported

If “Other” describe:

Jurisdiction Has a Mandatory Food Protection Manager Certification Requirement (Select **ONE** of the following):

- YES – Based **ONLY** on successful completion of an ANSI-Accredited Program
- YES – Other Food Protection Manager Certification Program (not an ANSI-Accredited Program)
- YES – Other **AND** Reciprocal Acceptance of an ANSI Accredited Program
- NO – Jurisdiction does not have a mandatory Food Protection Manager Certification Requirement

If “Other” describe:

If “Other” (Select **ONE** of the following)

- Other includes a required Training Component
- Other includes a Test other than exams offered through an ANSI Accredited Programs
- Other includes a required Training Component **AND** Test other than exam offered through an ANSI Accredited Program

INFORMATION ON THE REGULATORY AUTHORITY (continued from previous page)

Scope of Food Protection Manager Certification Requirement (Select ONE of the following):

- Person in Charge – One Per Establishment
- Person in Charge – Present at All Times
- Supervisory Employee – One Per Establishment
- Supervisory Employee – Present at All Times
- Other

If "Other" describe:

Jurisdiction Requires Food Handler Card (Select ONE of the following):

- YES – Required Training
- YES – Required Test
- YES – Required Training and Test
- YES – Other
- NO – Jurisdiction does NOT require Food Handler Cards

If "Other" describe:

MOST RECENT ROUTINE INSPECTIONS

Dates of the Two Most Recent Regulatory Routine Inspections: Date 1: Date 2:

MANAGER CERTIFICATION

1. Is there a certified food protection manager EMPLOYED at the establishment (Select ONE)?

- YES – Certificate Available
- YES – Certificate NOT Available
- NO – No certified food protection managers are employed at the establishment

If the marking above contains a “YES” response, indicate the Type of Certification below (Select ONE)

- ANSI-Accredited
- Other
- Unsure

2. Is there an employee who is a certified food protection manager PRESENT during the data collection (Select ONE)?

- YES – Certificate Available
- YES – Certificate NOT Available
- NO – No certified food protection managers are present during the data collection

If the marking above contains a “YES” response, indicate the Type of Certification below (Select ONE)

- ANSI-Accredited
- Other
- Unsure

3. Is the PERSON IN CHARGE at the time of the data collection a certified food protection manager (Select ONE)?

- YES – Certificate Available
- YES – Certificate NOT Available
- NO – The person in charge at the time of the data collection is NOT a certified food protection manager

If the marking above contains a “YES” response, indicate the Type of Certification below (Select ONE)

- ANSI-Accredited
- Other
- Unsure

4. Is the establishment’s policy to have a certified food protection manager present at all times?
YES NO

If “Other” for one or more of the responses to questions 1 – 3, describe:

EMPLOYEE HEALTH POLICY

1. 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.

- YES – Employees exhibiting illness symptoms or conditions observed within the establishment
- NO – Employees exhibiting illness symptoms or conditions NOT observed within the establishment

2. 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*?

- YES – Policy is ORAL and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is ORAL and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- NO – Policy only partially developed or non-existent

3. Are food employees and conditional employees informed of their responsibility to report to the person in charge diagnosis with, or exposure to, the specific **ILLNESSES** specified in Section 2-201.11 of the *Food Code*?

- YES – Policy is ORAL and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is ORAL and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- NO – Policy only partially developed or non-existent

4. 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*?

- YES – Policy is ORAL and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is ORAL and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- NO – Policy only partially developed or non-existent

EMPLOYEE HEALTH POLICY (continued from previous page)

5. 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?

- YES – Policy is ORAL and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is ORAL and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- NO – Policy only partially developed or non-existent

6. 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?

- YES – Policy is ORAL and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is ORAL and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2013 *Food Code* (includes non-typhoidal Salmonella)
- YES – Policy is WRITTEN and based on the 2009 *Food Code* (does not include non-typhoidal Salmonella)
- NO – Policy only partially developed or non-existent

7. Management has a copy of FDA's *Employee Health and Personal Hygiene Handbook* OR *cd* database?

- YES
- NO

**Risk Factor – Poor Personal Hygiene
(Data Items 1 & 2)**

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			1. Employees practice proper handwashing
IN	OUT	NO	NA	Description of HANDWASHING OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. Hands are cleaned and properly washed using hand cleanser / water supply / appropriate drying methods / length of time as specified in Section 2-301.12 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>			B. Hands are cleaned and washed when required as specified in Section 2-301.14 of the <i>Food Code</i>
COMMENTS: <input type="checkbox"/>				

HANDWASHING FREQUENCY ASSESSMENT			
	<u>C1</u>	<u>C2</u>	<u>C3</u>
	Employee observed washing hands properly and when required	Employee observed washing hands improperly	Employee observed failing to wash hand when required
TOTAL COUNT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT											
PROCEDURES				TRAINING				MONITORING			
<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:	
<input type="checkbox"/>	2			<input type="checkbox"/>	2			<input type="checkbox"/>	2		
<input type="checkbox"/>	3			<input type="checkbox"/>	3			<input type="checkbox"/>	3		
<input type="checkbox"/>	4			<input type="checkbox"/>	4			<input type="checkbox"/>	4		
<input type="checkbox"/>	NA			<input type="checkbox"/>	NA			<input type="checkbox"/>	NA		

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			2. Food employees do not contact ready-to-eat foods with bare hands
COMMENTS:				

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT											
PROCEDURES				TRAINING				MONITORING			
<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:	
<input type="checkbox"/>	2			<input type="checkbox"/>	2			<input type="checkbox"/>	2		
<input type="checkbox"/>	3			<input type="checkbox"/>	3			<input type="checkbox"/>	3		
<input type="checkbox"/>	4			<input type="checkbox"/>	4			<input type="checkbox"/>	4		
<input type="checkbox"/>	NA			<input type="checkbox"/>	NA			<input type="checkbox"/>	NA		

**Risk Factor – Contaminated Equipment/Protection from Contamination
(Data Items 3 & 4)**

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Food is protected from cross-contamination during storage, preparation, and display
IN	OUT	NO	NA	Description of FOOD Contamination OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw animal foods are separated from ready-to-eat foods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Different raw animal foods are separated from each other
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Food is protected from environmental contamination – actual contamination observed
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Food is protected from environmental contamination – potential contamination
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Other (<i>describe in the comments section below</i>)
COMMENTS: <input type="checkbox"/>				

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT											
PROCEDURES				TRAINING				MONITORING			
<input type="checkbox"/>	1	COMMENTS: <input type="checkbox"/>		<input type="checkbox"/>	1	COMMENTS: <input type="checkbox"/>		<input type="checkbox"/>	1	COMMENTS: <input type="checkbox"/>	
<input type="checkbox"/>	2			<input type="checkbox"/>	2			<input type="checkbox"/>	2		
<input type="checkbox"/>	3			<input type="checkbox"/>	3			<input type="checkbox"/>	3		
<input type="checkbox"/>	4			<input type="checkbox"/>	4			<input type="checkbox"/>	4		
<input type="checkbox"/>	NA			<input type="checkbox"/>	NA			<input type="checkbox"/>	NA		

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Food contact surfaces are properly cleaned and sanitized
IN	OUT	NO	NA	Description of Food Contact Surfaces OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Food contact surfaces and utensils are clean to sight and touch and sanitized before use
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Equipment food contact surfaces and utensils are cleaned and sanitized properly using manual warewashing procedures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Equipment food contact surfaces and utensils are cleaned and sanitized properly using mechanical warewashing equipment
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Other (<i>describe in the comments section below</i>)
COMMENTS: <input type="checkbox"/>				

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT											
PROCEDURES				TRAINING				MONITORING			
<input type="checkbox"/>	1	COMMENTS: <input type="checkbox"/>		<input type="checkbox"/>	1	COMMENTS: <input type="checkbox"/>		<input type="checkbox"/>	1	COMMENTS: <input type="checkbox"/>	
<input type="checkbox"/>	2			<input type="checkbox"/>	2			<input type="checkbox"/>	2		
<input type="checkbox"/>	3			<input type="checkbox"/>	3			<input type="checkbox"/>	3		
<input type="checkbox"/>	4			<input type="checkbox"/>	4			<input type="checkbox"/>	4		
<input type="checkbox"/>	NA			<input type="checkbox"/>	NA			<input type="checkbox"/>	NA		

**Risk Factor – Improper Holding/Time and Temperature
(Data Items 5-8)**

IN	OUT	NO	NA				
<input type="checkbox"/>	<input type="checkbox"/>			5. Foods requiring refrigeration are held at the proper temperature			
IN	OUT	NO	NA	Description of Cold Holding Temperature OBSERVATIONS			
<input type="checkbox"/>	<input type="checkbox"/>			A. TCS Food is maintained at 41°F (5°C) or below, except during preparation, cooking, cooling, or when time is used as a public health control			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Raw shell eggs are stored under refrigeration that maintains ambient air temperature of 45°F (7°C) or less			
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other (describe in the temperature chart and comments section below)			
COMMENTS:							
Cold Holding Temperatures Recorded During the Data Collection (List all temperatures taken)							
FOOD PRODUCT	FOOD TEMP.	FOOD CODE CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT	FOOD PRODUCT	FOOD TEMP.	FOOD CODE CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT
NUMBER OF FOOD PRODUCT TEMPERATURES				SUMMARY COLD HOLDING PRODUCT TEMPERATURE CATEGORIES			
				I. – Number of product temperature measurements IN Compliance with <i>Food Code</i> critical limits			
				II. – Number of OUT of Compliance product temperature measurements 1°F - 2°F above <i>Food Code</i> critical limits			
				III. – Number of OUT of Compliance product temperature measurements 3°F - 4°F above <i>Food Code</i> critical limits			
				IV. – Number of OUT of Compliance product temperature measurements 5°F - 9°F above <i>Food Code</i> critical limits			
				V. – Number of OUT of Compliance product temperature measurements 10°F or more above <i>Food Code</i> critical limits			
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT							
PROCEDURES				TRAINING		MONITORING	
<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:	
<input type="checkbox"/>	2						
<input type="checkbox"/>	3						
<input type="checkbox"/>	4						
<input type="checkbox"/>	NA						
<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:	
<input type="checkbox"/>	2						
<input type="checkbox"/>	3						
<input type="checkbox"/>	4						
<input type="checkbox"/>	NA						

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Foods displayed or stored hot are held at the proper temperature
IN	OUT	NO	NA	Description of Hot Holding Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. TCS Food is maintained at 135°F (57°C) or above, except during preparation, cooking, cooling, or when time is used as a public health control.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Roasts are held at a temperature of 130°F (54°C) or above
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Other (describe in the temperature chart and comments section below)

COMMENTS:

Hot Holding Temperatures Recorded During the Data Collection (List all temperatures taken)

FOOD PRODUCT	FOOD TEMP.	FOOD CODE CRITICAL LIMIT	TYPE OF HOT HOLDING EQUIPMENT	FOOD PRODUCT	FOOD TEMP.	FOOD CODE CRITICAL LIMIT	TYPE OF HOT HOLDING EQUIPMENT

NUMBER OF FOOD PRODUCT TEMPERATURES	SUMMARY HOT HOLDING PRODUCT TEMPERATURE CATEGORIES
	I. – Number of product temperature measurements IN Compliance with <i>Food Code</i> critical limits
	II. – Number of OUT of Compliance product temperature measurements 1°F - 2°F below <i>Food Code</i> critical limits
	III. – Number of OUT of Compliance product temperature measurements 3°F - 4°F below <i>Food Code</i> critical limits
	IV. – Number of OUT of Compliance product temperature measurements 5°F - 9°F below <i>Food Code</i> critical limits
	V. – Number of OUT of Compliance product temperature measurements 10°F or more below <i>Food Code</i> critical limits

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES		TRAINING		MONITORING	
<input type="checkbox"/>	1	<input type="checkbox"/>	1	<input type="checkbox"/>	1
<input type="checkbox"/>	2	<input type="checkbox"/>	2	<input type="checkbox"/>	2
<input type="checkbox"/>	3	<input type="checkbox"/>	3	<input type="checkbox"/>	3
<input type="checkbox"/>	4	<input type="checkbox"/>	4	<input type="checkbox"/>	4
<input type="checkbox"/>	NA	<input type="checkbox"/>	NA	<input type="checkbox"/>	NA
COMMENTS:		COMMENTS:		COMMENTS:	

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Foods are cooled properly
IN	OUT	NO	NA	Description of Cooling Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Cooked TCS Food is cooled from 135°F (57°C) to 70°F (21°C) within 2 hours and from 135°F (57°C) to 41°F (5°C) or below within 6 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Proper cooling methods / equipment are used
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

COMMENTS:

Cooling Temperatures Recorded During the Data Collection (List all temperatures taken)

FOOD PRODUCT	FOOD COOLING TEMP. #1	FOOD COOLING TEMP. #2	TOTAL TIME IN MINUTES	FOOD CODE CRITICAL LIMIT	TYPE OF EQUIPMENT USED TO COOL FOOD

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES		TRAINING		MONITORING	
<input type="checkbox"/>	1	<input type="checkbox"/>	1	<input type="checkbox"/>	1
<input type="checkbox"/>	2	<input type="checkbox"/>	2	<input type="checkbox"/>	2
<input type="checkbox"/>	3	<input type="checkbox"/>	3	<input type="checkbox"/>	3
<input type="checkbox"/>	4	<input type="checkbox"/>	4	<input type="checkbox"/>	4
<input type="checkbox"/>	NA	<input type="checkbox"/>	NA	<input type="checkbox"/>	NA
COMMENTS:		COMMENTS:		COMMENTS:	

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening
IN	OUT	NO	NA	Description of Date Marking OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Ready-to-eat, TCS Food (prepared on-site) held for more than 24 hours is date marked as required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Open commercial containers of prepared ready-to-eat TCS Food held for more than 24 hours are date marked as required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Ready-to-eat, TCS Food prepared on-site and/or opened commercial container exceeding 7 days at $\leq 41^{\circ}\text{F}$ is discarded
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Other (describe in the temperature chart and comments section below)

COMMENTS:

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT											
PROCEDURES				TRAINING				MONITORING			
<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:	
<input type="checkbox"/>	2										
<input type="checkbox"/>	3										
<input type="checkbox"/>	4										
<input type="checkbox"/>	NA										
<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:		<input type="checkbox"/>	1	COMMENTS:	
<input type="checkbox"/>	2										
<input type="checkbox"/>	3										
<input type="checkbox"/>	4										
<input type="checkbox"/>	NA										

**Risk Factor – Inadequate Cooking
(Data Items 9 & 10)**

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Raw animal foods are cooked to required temperatures
IN	OUT	NO	NA	Description of Cooking Temperature OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Raw shell eggs broken for immediate service are cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Pork; Fish; Beef; Commercially-raised Game Animals are cooked to 145°F (63°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Comminuted Fish, Meats, Commercially-raised Game Animals are cooked to 155°F (68°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Poultry; stuffed fish; stuffed meat; stuffed pasta; stuffed poultry; stuffed ratite; or stuffing containing fish, meat, poultry, or ratites; wild game animals are cooked to 165°F (74°C) for 15 seconds
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specifies and according to oven parameters per Chart <i>(NOTE: This data item includes beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham).</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Other Cooking Observations (describe in the Comment Section and Temperature Chart below)
COMMENTS: <input type="checkbox"/>				

Cooking Temperatures Recorded During the Data Collection (List all temperatures taken)

FOOD PRODUCT	FINAL COOK TEMP.	FOOD CODE CRITICAL LIMIT	CONSUMER ADVISORY		FOOD PRODUCT	FINAL COOK TEMP.	FOOD CODE CRITICAL LIMIT	CONSUMER ADVISORY	
			YES	NO				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>

NUMBER OF FOOD PRODUCT TEMPERATURES	SUMMARY COOKING FOOD PRODUCT TEMPERATURE CATEGORIES
	I. – Number of product temperature measurements IN Compliance with <i>Food Code</i> critical limits
	II. – Number of OUT of Compliance product temperature measurements 1°F - 2°F below <i>Food Code</i> critical limits
	III. – Number of OUT of Compliance product temperature measurements 3°F - 4°F below <i>Food Code</i> critical limits
	IV. – Number of OUT of Compliance product temperature measurements 5°F - 9°F below <i>Food Code</i> critical limits
	V. – Number of OUT of Compliance product temperature measurements 10°F or more below <i>Food Code</i> critical limits

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES		TRAINING		MONITORING	
<input type="checkbox"/>	1	<input type="checkbox"/>	1	<input type="checkbox"/>	1
<input type="checkbox"/>	2	<input type="checkbox"/>	2	<input type="checkbox"/>	2
<input type="checkbox"/>	3	<input type="checkbox"/>	3	<input type="checkbox"/>	3
<input type="checkbox"/>	4	<input type="checkbox"/>	4	<input type="checkbox"/>	4
<input type="checkbox"/>	NA	<input type="checkbox"/>	NA	<input type="checkbox"/>	NA
COMMENTS:		COMMENTS:		COMMENTS:	

IN	OUT	NO	NA						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Cooked foods are reheated to required temperatures					
IN	OUT	NO	NA	Description of Reheating Temperature OBSERVATIONS					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. TCS Food that is cooked and cooled on premises is rapidly reheated to 165°F (74°C) for 15 seconds for hot holding					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Commercially-processed ready-to-eat food, reheated to 135°F (57°C) or above for hot holding					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Other Reheating Observations (describe in the Comments Section and Temperature Chart below)					
COMMENTS:									
Reheating Temperatures Recorded During the Data Collection (List all temperatures taken)									
FOOD PRODUCT	FINAL REHEAT TEMP.	FOOD CODE CRITICAL LIMIT	FOOD PRODUCT	FINAL REHEAT TEMP.	FOOD CODE CRITICAL LIMIT				
NUMBER OF FOOD PRODUCT TEMPERATURES			SUMMARY COOKING FOOD PRODUCT TEMPERATURE CATEGORIES						
			I. – Number of product temperature measurements IN Compliance with <i>Food Code</i> critical limits						
			II. – Number of OUT of Compliance product temperature measurements 1°F - 2°F below <i>Food Code</i> critical limits						
			III. – Number of OUT of Compliance product temperature measurements 3°F - 4°F below <i>Food Code</i> critical limits						
			IV. – Number of OUT of Compliance product temperature measurements 5°F - 9°F below <i>Food Code</i> critical limits						
			V. – Number of OUT of Compliance product temperature measurements 10°F or more below <i>Food Code</i> critical limits						
FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT									
PROCEDURES		TRAINING		MONITORING					
<input type="checkbox"/>	1	<input type="checkbox"/>	1	<input type="checkbox"/>	1				
COMMENTS:		COMMENTS:		COMMENTS:					
						<input type="checkbox"/>	2	<input type="checkbox"/>	2
						<input type="checkbox"/>	3	<input type="checkbox"/>	3
						<input type="checkbox"/>	4	<input type="checkbox"/>	4
						<input type="checkbox"/>	NA	<input type="checkbox"/>	NA

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			11. Handwashing facilities are accessible and properly maintained
IN	OUT	NO	NA	Description of OBSERVATIONS of Handwashing Facilities
<input type="checkbox"/>	<input type="checkbox"/>			A. Handwashing facilities are conveniently located and accessible for employees
<input type="checkbox"/>	<input type="checkbox"/>			B. Handwashing facilities are supplied with hand cleanser / disposable towels / hand drying devices
COMMENTS: <input type="checkbox"/>				

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			12. Employees practice good hygiene
IN	OUT	NO	NA	Description of Good Hygienic Practices OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. Food Employees eat, drink, and use tobacco only in designated areas
<input type="checkbox"/>	<input type="checkbox"/>			B. Food Employees experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service, or single-use articles
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other (<i>describe in Comments Section below</i>)
COMMENTS:				

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	13. Consumers are properly advised of risks of consuming raw or undercooked animal foods
COMMENTS:				

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14. Time alone is properly used as a public health control
IN	OUT	NO	NA	Description of Time as a public health control OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. When time only is used as a public health control for 4 HOURS , the food establishment follows procedures to serve or discard food as specified in Section 3-501.19 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. When time only is used as a public health control for 6 HOURS , the food establishment follows procedures to serve or discard food as specified in Section 3-501.19 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Other (describe in the comments section below)
COMMENTS:				

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15. Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces
IN	OUT	NO	NA	Description of OBSERVATIONS for temperature control
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Refrigeration / cold holding units have sufficient capacity to maintain TCS Foods at 41°F (5°C) or below
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Hot holding units have sufficient capacity to maintain TCS Foods at 135°F (57°C) or above
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Refrigeration and hot storage units are equipped with accurate ambient air temperature measuring device
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Accurate temperature measuring device, with appropriate probe, is provided and accessible for use to measure internal food temperatures
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Accurate temperature measuring devices and/or tests kits provided and accessible for use to measure sanitization rinse temperatures and/or sanitization concentrations
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Other (describe in the comments section below)
COMMENTS:				

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16. Special processes are conducted in compliance with issued variance / HACCP Plan, when required
IN	OUT	NO	NA	Description of OBSERVATIONS of Specialized Processes
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. Food establishment conducts reduced oxygen packaging without a variance as specified in Section 3-502.12 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Food establishment performs specialized process in accordance with approved variance and HACCP Plan when required
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Juice packaged in the food establishment is treated under a HACCP Plan to reduce pathogens or labeled as specified in Section 3-404.11 of the <i>Food Code</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. Other (describe in the comments section below)
COMMENTS:				

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17. Food is received from safe sources
IN	OUT	NO	NA	Description of FOOD SOURCE OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A. All food is from regulated food processing plants / No home prepared/canned foods
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	B. Shellfish are from NSSP-listed sources. No recreationally caught shellfish are received/sold
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	C. Food is protected from contamination during transportation/receiving
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	D. TCS Food is received at a temperature of 41°F (5°C) or below OR according to Law
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	E. Food is safe and unadulterated
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	F. Shellstock tags/labels are retained for 90 days and filed in chronological order from the date the container is emptied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	G. Written documentation of parasite destruction is maintained for 90 days for fish products
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	H. Other (<i>describe in Comments Section below</i>)
COMMENTS:				

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			18. Toxic materials are identified, used, and stored properly
IN	OUT	NO	NA	Description of Toxic Materials OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are properly identified, stored, and used
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	B. Other (<i>describe in the comments section below</i>)
COMMENTS:				

IN	OUT	NO	NA	
<input type="checkbox"/>	<input type="checkbox"/>			19. Management and food employees are trained in food allergy awareness as it relates to their assigned duties
IN	OUT	NO	NA	Description of Allergen Awareness OBSERVATIONS
<input type="checkbox"/>	<input type="checkbox"/>			A. The person in charge accurately describes foods identified as major food allergens and the symptoms associated with major food allergens
<input type="checkbox"/>	<input type="checkbox"/>			B. Food employees are trained in food allergy awareness as it relates to their assigned duties
<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	C. Other (<i>describe in the comments section below</i>)
COMMENTS:				

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 food service, 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:

<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/default.htm>

Public Reporting burden of this collection of information is estimated to average 73 minutes per response for the person in charge 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. PRASStaff@fda.hhs.gov. OMB Control #0910-0744. Expires August 13, 2015.

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,

APPENDIX C: LIMITATIONS

Field Operations

The restaurant industry is dynamic. There is no set pattern of operation within a restaurant upon which a data collection protocol can be established that will ensure an opportunity to observe all food safety practices and employee behaviors covered in this study. 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 restaurants. 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 specialist'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. 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 restaurant data collection period reduced the variations in observations of data items that occurred during the previous study. Of the 10 primary data items, two 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 specialists conducted the data collections at restaurant facilities. The specialists are geographically dispersed throughout the United States. The geographic distribution of specialists 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 specialist's home location.

The total number of establishments in the country is approximately 472,243 and the total number within the sampling zones is 295,003. Roughly 62% 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 2012. 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.

For restaurant data, ESRI used Infogroup's proprietary six-digit Standards Industrial Classification (SIC) and eight-digit North American Industry Classification System (NAICS) industry codes and a special industry code for some restaurants. It represented comprehensive restaurant records based on a single restaurant per location.

Restaurant addresses are geocoded to assign latitude and longitude coordinates to each restaurant site. The quality of the local address system varies; 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 codes were used to perform spatial sampling for the risk factor study.

The geographical distribution of specialists 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

specialists' 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 the restaurant industry using multiple data collection periods. The way the samples were selected and the size of the dataset do not support comparisons of individual specialists' 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.

FDA tracked the actual time spent to complete data collection at each restaurant. The average time to complete data collection in fast food and full-service restaurants was 82 and 104 minutes, respectively. 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 THE RESTAURANT INDUSTRY

To assess trends over time three data points, at a minimum, are required for statistical purposes. The data from this report and two restaurant data collection periods in 2017 and 2021 will be used to determine trends in the occurrence of risk factors over the 10-year study period.

The initial restaurant data collection period began in November 2013 and was completed in early October 2014. This report highlights the statistically significant findings from that data collection period. Table 28 provides a summary of the 10-year study time frames for the restaurant data collection periods.

Table 28 Summary of Data Collection Time Frames for the Restaurant Industry

Industry Segment	Facility Type	Initial Data Collection Period (Baseline Measurement)	2ND Data Collection Period	3RD Data Collection Period
Restaurants	Full-service Restaurants and Fast Food Restaurants	Nov. 15, 2013 to Sept. 30, 2014	Oct. 1, 2017 to Sept. 30, 2018	Oct. 1, 2021 to Sept. 30, 2022

APPENDIX E: SUPPLEMENTAL STATISTICAL ANALYSIS

The Biostatistics and Bioinformatics Staff has analyzed the data from the Foodborne Illness Risk Factors Study utilizing a main effects multi-factor ANOVA. We found that the primary factor associated with improved compliance is Food Safety Management Systems (PTM) for both Full- Service and Fast Food establishments. In the analysis of Fast Food restaurants, the factor Multi-Unit was also predictive of the out-of-compliance rate. In the Full-service analysis, there were statistically significant main effect P-values in the model for PTM, Risk category, Enrolled in program standards, Jurisdiction requires grading and Jurisdiction requires food handler card.

Reasons for performing the regression analysis:

Many factors were measured in the Foodborne Risk Factors Study and several have statistically significant ($p < 0.05$) pairwise correlations with each other as seen in tables 20 and 21, page 33-34 of the study. 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 are predictive of improved compliance when the set of correlated predictors are in the model. If a pairwise correlation becomes non-significant in the ANOVA model, we say the pair-wise correlation is 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 12 with all the variables and then each variable was removed from the full model in order to assess the effect on the change in model R-squared upon removal. The R-squared represents the amount of variance in the response variable that is explained by the model. If there is minimal change in the model R-square upon removal of a predictor, it means that the correlation between the response and the variable can be explained by other variables in the model. If there is a significant reduction in R-squared upon removal, it indicates that the predictor in question has statistical explanatory power that is not explained by the other variables. We also report the P-values of the F statistic. P-values greater than 0.05 are not generally considered to be statistically significant. The data from *Full-service* and *Fast Food* restaurants were analyzed separately.

Table 29 Fast Food Restaurants multi-factor ANOVA

Fast Food	Model R-square	Reduction in R-Square	% R-square reduction	Prob > F
Model with all parameters	0.228932			
Management systems (PTM)(FSMS)	0.184372	0.044560	19.46%	<0.0001
Multiple-Unit	0.189742	0.039190	17.12%	<0.0001
Risk category	0.221951	0.006981	3.05%	0.1620
Certified Manager(CFPM)	0.226928	0.002004	0.88%	0.7892
Enrolled in program standards	0.224659	0.004273	1.87%	0.1354
Jurisdiction requires CFPM	0.226494	0.002438	1.06%	0.2591
Jurisdiction requires grading	0.223994	0.004938	2.16%	0.1085
Jurisdiction requires reporting	0.227919	0.001013	0.44%	0.4668
Jurisdiction requires food handler card	0.228899	0.000033	0.01%	0.8964

For fast food restaurants removing only the variable “Management systems (PTM) (FSMS)” from the model resulted in a reduction of R-square of 19.46%. Removing only the variable “multiple-unit” resulted in a 17.12% reduction in R-squared. The removal of any of the other variables from the model had a negligible effect on the R-square. Removing both “PTM (FSMS)” and “multiple-unit” resulted in a 67.83% reduction in R-squared.

The average out of compliance for establishments with nonexistent management systems was 4.48 primary data items out of compliance while those with well-developed and documented managements systems had 1.70 primary data out of compliance. In this analysis, only the predictors Management systems (PTM) and Multiple-unit had statistically significant effects on the model predictions, with both significant at the $p < 0.0001$ level.

Table 30 Full-service restaurants multi-factor ANOVA

Full-service	Model R-square	Reduction in R-Square	% R-square reduction	Prob > F
Model with all parameters	0.221845			
Management systems (PTM)(FSMS)	0.113826	0.108019	48.69%	<0.0001
Multiple-Unit	0.221720	0.000125	0.06%	0.8044
Risk category	0.206260	0.015585	7.03%	0.0096
Certified Manager (CFPM)	0.209423	0.012422	5.60%	0.1096
Enrolled in program standards	0.213041	0.008804	3.97%	0.0385
Jurisdiction requires CFPM	0.219152	0.002693	1.21%	0.2516
Jurisdiction requires grading	0.207173	0.014672	6.61%	0.0077
Jurisdiction requires reporting	0.221249	0.000596	0.27%	0.5894
Jurisdiction requires food handler card	0.211421	0.010424	4.70%	0.0244

In the Full-service restaurants the removal of the variable “Management systems (PTM) (FMSM)” resulted in a 48.69% reduction in the R-squared. The removal of any of the other variables had a negligible effect on the R-squared.

The average out of compliance for establishments with nonexistent Food safety management systems was 5.84 primary data items out of compliance while those with well-developed and documented managements systems had 2.09 primary data out of compliance.

Effect of Certified food protection managers (CFPM) on Food safely management systems (FSMS):

It is important to note that CFPM category does not have a statistically significant effect on the number of data items out of compliance when FSMS is included in the model. However there is evidence to suggest that the presence of a certified manager is correlated with improved management systems:

Fast Food restaurants:

There is a relationship between the Certified manager status and the Management systems (PTM)(FSMS). Facilities that had either a certified manager present or a certified manager who was the person in charge (PIC) at the time of inspection had a far higher percentage of well developed or better management systems than those that had no certified manager present at the time of inspection. Facilities that had a certified

manager present or in charge had almost half of the establishments with well developed or better management systems (PTM) while those that did not had far less.

Fast Food	Management systems (PTM)			
	Non-Existent	Underdeveloped	Well developed	Well developed and documented
Certified Manager = Employed	16.98%	50.94%	26.42%	5.66%
Certified Manager = None	24.05%	64.56%	10.13%	1.27%
Certified Manager = PIC	9.96%	42.80%	33.95%	13.28%
Certified Manager = Present	6.25%	43.75%	31.25%	18.75%

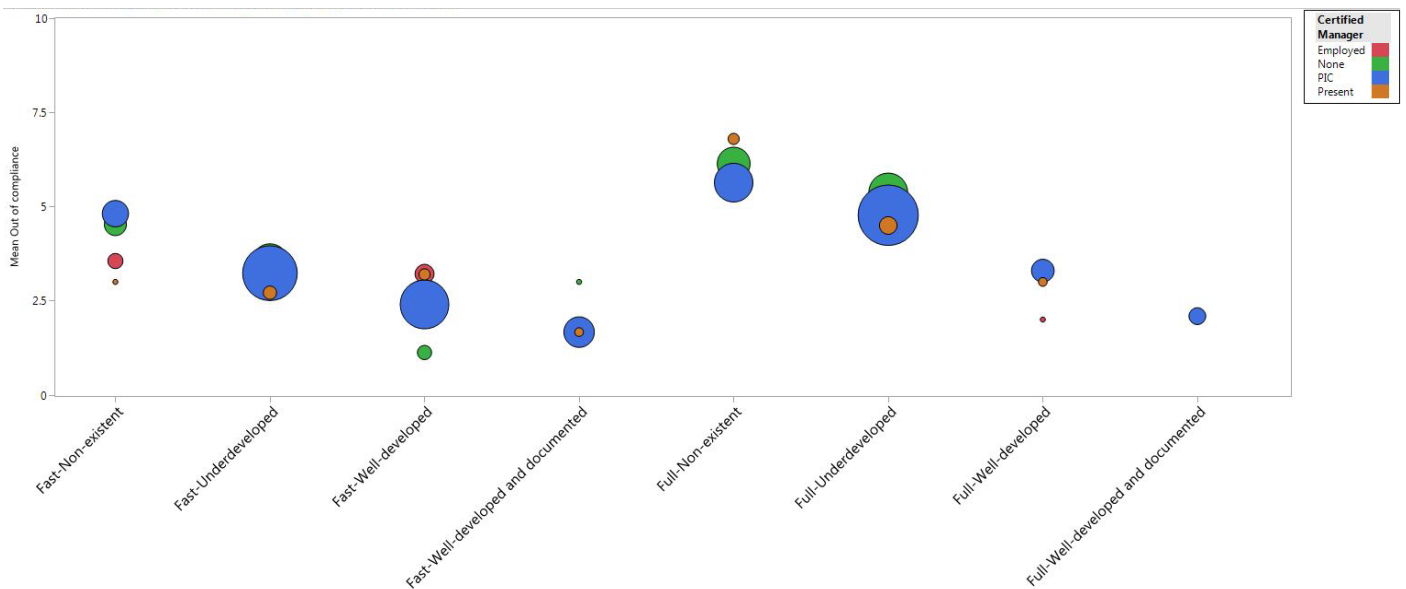
Full-service Restaurants:

There is a relationship between the certified manager status and the management systems (PTM) (FSMS). Facilities that had a certified manager present or in charge had a far higher percentage of well developed or better management systems than those that had no certified manager present at the time of inspection.

Full Service	Management systems (PTM)			
	Non-Existent	Underdeveloped	Well developed	Well developed and documented
Certified Manager = Employed	42.22%	55.56%	2.22%	0.00%
Certified Manager = None	41.58%	58.42%	0.00%	0.00%
Certified Manager = PIC	25.22%	61.30%	8.70%	4.78%
Certified Manager = Present	25.00%	60.00%	15.00%	0.00%

This plot of mean out of compliance by PTM (FSMS) and Certified manager level shows the relationship between food safety management systems, certified manager status and compliance. For both fast food and full-service restaurants the out of compliance decreases as the management systems improve. Most establishments in the study had certified managers in charge at the time of inspection. These are represented in blue and contain the most area in the plot. Most of the establishments in both fast food and Full-service restaurants that had well developed or well developed and documented management systems had a certified manager who was the person in charge (PIC) at the time of inspection.

Figure 2 Bubble Plot of Mean Out of Compliance by Food Safety Management System



An analysis of LS-means for fast food and full-service restaurants describes the quantitative effect size for PTM and for Certified manager level, adjusting for the other model parameters. Factors sharing a letter are not statistically different. The largest difference of 3.55 out of compliance units came between “Non-existent” and “Well developed and documented” PTM in the Full-service group. The only statistically significant difference for Certified Manager was in Full-service between “None” and “Present.”

	PTM Management Level		LS Mean Out of Compliance
Fast Food	Non-Existent	A	3.92
	Underdeveloped	AB	3.44
	Well-developed	BC	2.92
	Well developed and documented	C	2.16
Full Service	Non-Existent	A	4.68
	Underdeveloped	B	3.97
	Well-developed	C	2.37
	Well developed and documented	C	1.13
	Certified Manager Level		LS Mean Out of Compliance
Fast Food	None	A	3.3
	Employed	A	3.15
	PIC	A	3.07
	Present	A	2.92
Full Service	None	A	3.42
	Employed	A B	3.2
	PIC	A B	2.77
	Present	B	2.76

In order to focus on the relationship between the Certified Manager factor and the PTM, three separate ANOVAs were run for both Full-service and Fast Food restaurants with PTM alone, PTM + Certified Manager Employed and PTM + Certified Manager Present. The results are shown in Tables 31 and 32 . For the full-service restaurant analysis, the PTM Management system factor explains about 20.7 % of the variance, r-square=0.2069, and the p-value for the PTM is $p < 0.0001$ so it is highly statistically significant regardless of the presence of the Certified Manager Employed or the Certified Manager Present being added to the model. On the other hand, adding the Certified Manager Present or Certified Manager Employed to the model improves the r-square minimally, and the test of significance of both factors are 0.09 fails to achieve statistical significance, which, where the standard threshold level is $p < 0.05$. In the case of the Fast Food, the PTM is always highly significant at $p < 0.0001$, while the Certified Manager Present or Certified Manager Employed are highly nonsignificant at $p=0.95$ and $p=0.77$ respectively.

Table 31 ANOVA by Food Safety Management System: Full-service Restaurant

Model	Factor	P-value	R-square
PTM(FSMS), Certified Manager Employed	PTM(FSMS)	0.0001	0.2125
	CFPM employed	0.09 (NS)	
PTM(FSMS), Certified Manager Present	PTM(FSMS)	0.0001	0.2127
	CFPM Present	0.09 (NS)	
PTM (FSMS) only	PTM(FSMS)	0.0001	0.2069

Table 32 ANOVA by Food Safety Management System: Fast Food Restaurant

Model	Factor	P-value	R-square
PTM(FSMS), Certified Manager Employed	PTM (FSMS)	0.0001	0.178
	CFPM employed	0.77 (NS)	
PTM (FSMS), Certified Manager Present	PTM (FSMS)	0.0001	0.1781
	CFPM Present	0.95 (NS)	
PTM (FSMS) only	PTM(FSMS)	0.0001	0.178

These results, along with the full model and the bubble plots clearly demonstrate that there is a very strong association between Management Systems and In-compliance in this survey. The correlations seen with Certified Manager effects and compliance are explained by the fact that restaurants with good management systems are also more likely to employ Certified Managers or have them present at the time of inspection.

ACRONYMS/ABBREVIATIONS

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

Table 33 Acronyms and Abbreviations

Acronym	Meaning
AMC	active managerial control
BRC	British Retail Consortium
CDC	Centers for Disease Control and Prevention
CFPM	certified food protection manager
CFSAN	Center for Food Safety and Applied Nutrition
FDA	U.S. Food and Drug Administration
FSMS	food safety management system
GMP	good manufacturing practices
HACCP	hazard analysis and critical control points
NRA	National Restaurant Association
SQF	Safe Quality Food Institute
PTM	Procedures, Training and Monitoring
VNRFPS	Voluntary National Retail Food Regulatory Program Standards

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