U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program
Integrated Food Safety Systems
Office of Retail Food Protection

TECHNICAL REPORT: FDA REPORT ON THE OCCURRENCE OF FOODBORNE ILLNESS RISK FACTORS IN RETAIL FOOD STORE DELIS

2019-2022

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ACRONYMS/ABBREVIATIONS

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

AMC	Active Managerial Control
ANOVA	Analysis of Variance
ANSI	American National Standards Institute
CDC	Centers for Disease Control and Prevention
CFPM	Certified Food Protection Manager
ESRI	Environmental Systems Research Institute
FDA	U.S. Food and Drug Administration
FSMS	Food Safety Management Systems
HACCP	Hazard Analysis and Critical Control Points
HFP	Human Foods Program
TCS	Time/Temperature Control for Safety Food
PIC	Person in Charge
PTM	Procedures, Training, and Monitoring
RTE	Ready-to-Eat
PS	Voluntary National Retail Food Regulatory Program Standards
USDA	United States Department of Agriculture

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 delicatessen (delis) from 2019-2022. It is the second of three data collection periods for this retail sector that are part of the U.S. Food and Drug Administration's (FDA's) current study on trends in the occurrence of foodborne illness risk factors and food safety behaviors/practices in food service facilities. Data from the 2019-2022 collection will be used to assess trends in the occurrence of risk factors in future data collections. Of the foodborne illness risk factors investigated in this study, inadequate cooking was best controlled. The two most commonly occurring out-of-compliance risk factors were improper holding time/temperature and poor personal hygiene.

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

BACKGROUND

Foodborne illness remains a major public health concern in the United States. According to recent conservative estimates, based on Center for Disease Control and Prevention (CDC) surveillance of 7 major foodborne illness pathogens foodborne diseases cause 9.9 million cases of foodborne illness resulting in 53,300 hospitalizations and 931 deaths annually from domestically acquired foodborne illness (Walter, 2025). The annual economic burden from health losses due to foodborne illness is estimated at 90.2 billion dollars (Scharff, 2018).

The retail segment of industry employs 6 million workers and represents a combined annual sales volume of almost $800 billion (FMI, 2019). At the time of this data collection, there were approximately 78,919 retail food store establishments in the contiguous U.S. (ESRI, 2019).

The FDA's National Retail Food Risk Factor Study aims to observe behaviors across different segments of the retail food industry such as restaurants and delis to identify which foodborne illness risk factors are most out of control. These efforts and this report assist industry and regulators with prioritizing intervention strategies to control out of control risk factors.

In this report, delis were observed across the United States. For the purpose of our study delis are described as "areas in a retail food store where foods, such as luncheon meats and cheeses, are sliced for the customers and where sandwiches and salads are prepared on-site or received from a commissary in bulk containers, portioned, and displayed…" (see Table 1). These delis are unique in that they must reside in a retail food store (grocery store) and may have multiple regulatory authorities, whereas stand-alone delis are regulated solely by the U.S. Department of Agriculture (USDA).

According to the CDC, when considering incidents in 2017, retail food stores accounted for 21 outbreaks, 212 illnesses, 30 hospitalizations, and 1 death (CDC, 2017).

Delis have unique storage, handling, and service risks and opportunities. Most deli foods are ready-to-eat and receive no subsequent kill step for food safety such as cooking. This highlights the importance of maintaining good personal hygiene such as washing hands and no bare hand contact with ready-to-eatfood, due to the nature of the foods served.

Foodborne Illness Risk Factors

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

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

Tracking the occurrence of foodborne illness risk factors provides a consistent means of monitoring food safety and determining trends over time. Measuring and reporting on the

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

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

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

Purpose of the Study

The FDA is conducting a new 10-year study to investigate the relationship between Food Safety Management Systems (FSMS), the presence of a Certified Food Protection Manager (CFPM), and the occurrence of risk factors and food safety behaviors/practices commonly associated with foodborne illness at retail.

The objectives of this study are to:

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

FSMS refers to a specific set of actions used by food service establishments to help achieve active managerial control (AMC). Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification. While the components of FSMS vary across the retail and food service industry, purposeful implementation of procedures, training, and monitoring are consistent components of FSMS. There are several systems and tools available internationally to achieve AMC. Some of the most notable systems include International Organization for Standardization (ISO 22000), Good Manufacturing Practices, Hazard Analysis and Critical Control Points (HACCP), British Retail Consortium, and Safe Quality Food Institute (Codex, 2003; ISO 22000:2005, 2005; Luning et al., 2008). However, the ongoing prevalence and degree of implementation of these or similar

systems within retail food stores in the United States remains understudied. Inadequate FSMS are thought to contribute to the worldwide burden of foodborne disease (Luning et al., 2008). For example, HACCP has been shown to have positive effects on food safety. However, without robust procedures, training, and monitoring, poor implementation can occur. This poor implementation has been described as a precursor to foodborne outbreaks (Cormier, 2007; Luning et al., 2009; Ropkins & Beck, 2000).

A CFPM is an individual who has shown proficiency in food safety by passing a test that is part of an accredited program (FDA, 2017). Research has shown that the presence of a CFPM is associated with improved food safety knowledge and inspection scores (Cates et al., 2008; Brown et al., 2014).

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

- Develop retail food safety initiatives, policies, and targeted intervention strategies focused on controlling foodborne illness risk factor.
- 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.

Retail Food Store Deli Data Collection

This report describes the data collected in delis in 2019-2022. Data from this collection will be compared to baseline data collected in 2015 and used to assess trends in the occurrence of risk factors after a third data collection. When reviewing and analyzing the data, it is not appropriate to directly compare the results between this retail segment and other retail segments. The differences in operational variables, complexities of menus, operations, and procedures between each retail facility type create distinct environments that do not lend themselves to direct comparison. Additional information can be found in Appendix D of this report.

FDA acknowledges that this data collection occurred before and after a novel time of the COVID-19 pandemic. While we are interested in the impacts of the pandemic on food safety practices and behaviors, this study is not designed to detect differences in practices within a single data collection period. Once the third and final data collection in this industry segment is complete, FDA will issue a trends report. In that report, we plan to analyze the changes in practices over time to include any trends or anomalies within the pandemic time period and will report any findings of note.

Deli Departments and Handwashing

The retail environment is dynamic, with many foods coming together to produce a final product. This makes applying HACCP for each individual commodity challenging. For this reason, FDA suggests using a process approach to HACCP at retail for most handling practices. The process approach divides the food flows in an establishment into broad categories based on activities or stages in the flow of food through your establishment, then analyzing the hazards, and placing managerial controls on each grouping. Using this approach, most food items produced at retail can be grouped into one of three processes, which correspond with the number of times the food passes through the temperature danger zone between 41°F and 135°F (FDA, 2006).

Deli departments primarily serve ready-to-eat products. Using process HACCP as described above, it is important to focus efforts for foodborne illness prevention in process 1 (ready-to-eat or assemble and serve), on personal hygiene efforts such as employee health (excluding ill workers), handwashing (how to wash and when to wash), as well as prohibition of bare hand contact with ready-to-eat food. This is due to the absence of a kill step such as cooking. With this in mind, educational efforts, outreach, and compliance and enforcement in deli departments often focus interventions around preventing poor personal hygiene and enhancing employee health policies.

The FDA's educational effort to raise the awareness of the importance of employee health is ongoing. Additional education on employee health, handwashing and no bare hand contact with ready-to-eat foods includes an array of posters, videos, tools, and training (FDA2019e).

Studies on poor personal hygiene in food establishments indicated that there are positive impacts on handwashing behavior with the development of food safety management systems (Verrill, 2021). Other sources, such as the USDA guide on controlling Listeria monocytogenes and the CDC's overview of characteristics of outbreaks and contributing factors, also highlight the key role hand hygiene plays in preventing foodborne illness at retail (Brown et al., 2017).

Intervention Strategies and Factors of Interest

Active Managerial Control

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

Regulatory Authority Characteristics

Regulatory authorities at local, state, territorial, and tribal levels have a number of unique organizational and regulatory requirements and implementation and disclosure practices. These factors vary across jurisdictions and can include, among others, enrollment in the Voluntary National Retail Food Regulatory Program Standards (PS)[1] (FDA, 2019), implementation of grading systems (e.g., posting letter grades like A, B, and C), requirement for establishments to have a CFPM, and the publication of inspection results (e.g., posting inspection reports online). Including this information as part of the data collection provides an opportunity to assess how elements within a regulatory retail food protection program may influence the relationship between FSMS, CFPM, and the occurrence of risk factors and food safety behaviors/practices.

Retail Food Store Deli Characteristics

In addition to local jurisdictional requirements with which delis must comply, delis themselves differ in complexity of food preparation and organizational structure. For example, research has found that delis that are part of a multiple-unit operation (i.e., delis 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 deli in this data collection allows for assessing how the occurrence of food safety behaviors/practices in delis differs based on complexity of food preparation and status as a single-unit or multiple-unit operation.

[1] 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.

DESIGN AND METHODOLOGY

Study Design

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

In 2013, the FDA obtained Office of Management and Budget (OMB Control #0910-0799) approval to initiate the first phase of the study, which focused in part on data collection within the retail food store segment of the industry. For the purposes of this report, results from the deli departments will be reported. A description of a deli department can be found in Table 1.

Table 1. Description of a Deli Department

Department Type	Description
Deli Department	Areas in a retail food store where foods, such as luncheon meats and cheeses, are sliced for the customers and where sandwiches and salads are prepared on-site or received from a commissary in bulk containers, portioned, and displayed. Parts of the deli department/operation may include: • Salad bars, pizza stations, and other food bars managed by the deli department manager, and • Areas where meat and poultry products are cooked and offered for sale as ready-to-eat and are managed by the deli department manager.

Deli Eligibility

This study was intended to examine food safety practices in delis located in retail food stores. Retail food stores were randomly selected to participate in the study from among all eligible establishments located within a 175-mile radius from the home locations of the 26 FDA Retail Food Specialists performing the data collection. For this study, the complexity of food preparation was represented by the food establishment's risk categorization as found in Annex 5 of the 2017 FDA Food Code (see Table 2). This risk categorization was used to determine if an establishment was eligible for data collection. Retail food stores that only served pre-packaged food, or conducted low-risk food preparation activities, or only operated seasonally were ineligible for selection. Establishments eligible for study selection fell into risk categories 2 through 4, as these food establishments represent more complex food preparation activities.

Table 2. Risk Categorization of Food Establishments

Risk Category	Description
1	Examples include most convenience store operations, hot dog carts, and coffee shops. Establishments that serve or sell only pre-packaged non-time/temperature control for safety (TCS) foods. Establishments that prepare only non-TCS foods. Establishments that heat only commercially processed TCS foods for hot holding. No cooling of TCS foods. Establishments that would otherwise be grouped in Category 2 but have shown through historical documentation to have achieved AMC of foodborne illness risk factors.
2	Examples may include retail food store operations, schools not serving a highly susceptible population, and quick-service operations. Includes establishments with a 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 been shown through historical documentation to achieve active managerial control of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 1 until history of AMC of foodborne illness risk factors is achieved and documented.
3	An example is a deli. Extensive menu and handling of raw ingredients. Complex preparation including cooking, cooling, and reheating for hot holding involves many TCS foods. Variety of processes require hot and cold holding of TCS food. Establishments that would otherwise be grouped in Category 4 but have shown through historical documentation to have achieved AMC of foodborne illness risk factors. Newly permitted establishments that would otherwise be grouped in Category 2 until history of AMC of foodborne illness risk factors is achieved and documented.
4	Examples include preschools, hospitals, nursing homes, and establishments conducting processing at retail. Includes establishments that serve a highly susceptible population or that conduct specialized process, e.g., smoking and curing; reduced oxygen packaging for extended shelf-life.

Source: Annex 5, 2017 FDA *Food Code*.

Data Collection

All data collection was conducted by Retail Food Specialists who have technical expertise in food safety and a solid understanding of food service operations within the deli industry. The data collectors conducted site visits throughout the United States at randomly selected delis to perform data collections. All data collectors received customized training specific to the study data collection protocol and marking instructions for the data collection tool. FDA's Office of Retail Food Protection personnel standardized the data collectors in applying and interpreting the FDA Food Code utilizing the FDA Procedures for Standardization of Retail Food Safety Inspection Officers.

Deli Selection

A Geographic Information System database containing a listing of U.S. businesses was used to identify the inventory of delis for data collection. The total number of establishments in the country extracted from ESRI 2019 version Business Location geodatabase was approximately 78,919. Delis were randomly selected from among all eligible establishments located within a 175-mile radius of the home locations of the twenty-six data collectors. The number of establishments within the sampling zones was 55,275. As a result, roughly 70% of all establishments in the deli segment were eligible for selection. Figure 1 depicts the sample selection coverage area.

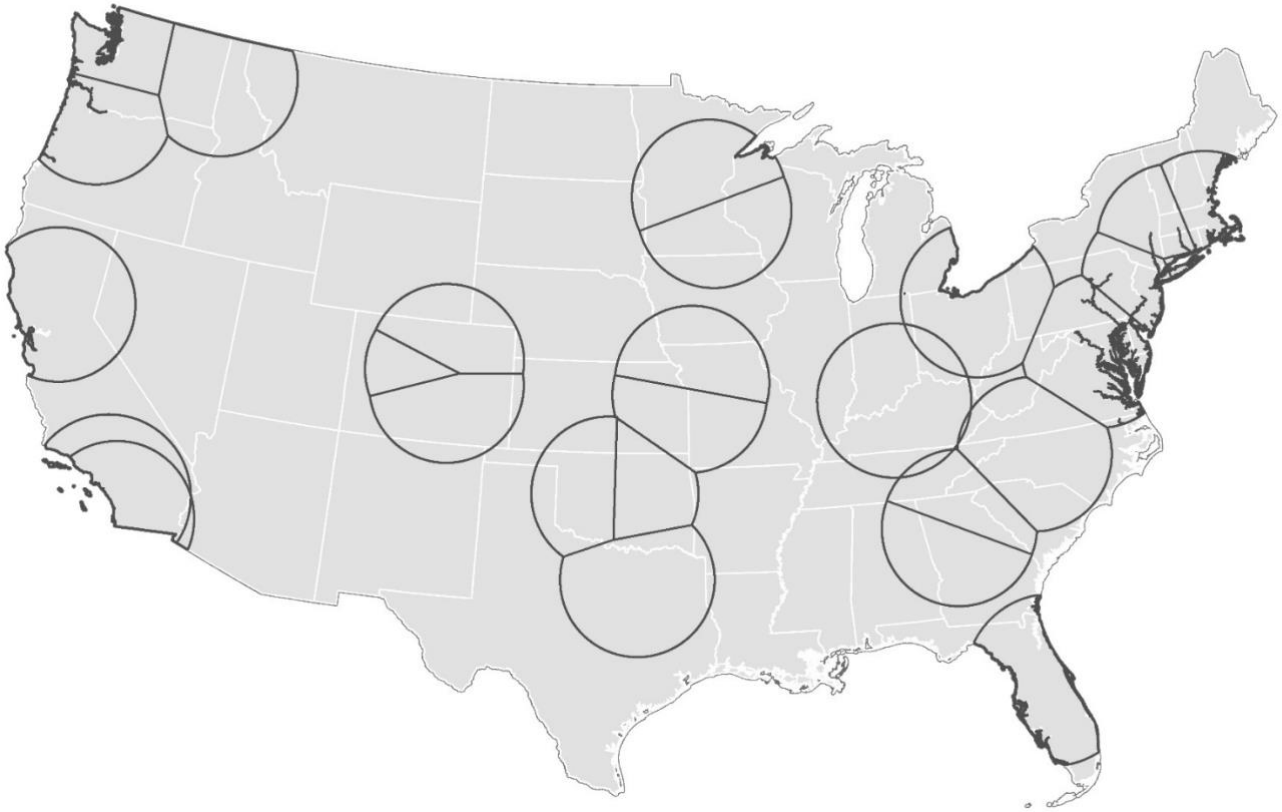


Figure 1 Sample Selection Coverage Areas

Sample Size and Confidence Interval

The Biostatistics Team determined that a minimum of 384 data collections in the deli facility type was needed during the initial and subsequent data collect periods to provide 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 438 data collections.

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

Study Protocol and Methodology

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

- Food and Drug Administration (2013b), Study on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2024– Protocol for the Data Collection.

- Food and Drug Administration (2013c), Retail Food Program Foodborne Illness Risk Factor Study – Marking Instructions for the Data Collection Form.

Eligibility Verification of Randomly Selected Delis

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

Regulatory Authorities of Selected Delis

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

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

Data Collection Protocol

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

The data collector used the current version of the Food Code (FDA, 2017a) as the standard of measurement for compliance markings for observations of employee food safety behaviors/practices. Quantitative measurements of food product temperatures, sanitizer concentrations, and dish machine final rinse temperatures were collected using calibrated equipment such as thermocouples, heat- sensitive tape, and maximum registering stem thermometers. Visual observations of food safety practices were supplemented by asking questions of food employees and/or managers to ensure data collectors had a clear understanding of food processes and procedures. The owner or PIC of the deli was encouraged to accompany the data collector during the data collection.

Risk Factors and Associated Data Items

This study focused on observation and/or measurement of food safety practices/behaviors associated with the occurrence of foodborne illness risk factors. Four foodborne illness risk factors, comprising specific food safety behaviors, were used as the key indicators for FDA's statistical analysis for this study. Data items in this study were based on the FDA Food Code, which represents FDA's best advice for a uniform system of provisions that address the safety and protection of food offered at retail and in food service (FDA, 2017a). Table 3 presents the 10 data items and their associated risk factors.

Although ensuring that food is obtained from an approved source is the first line of defense for delis, the current study design did not include this risk factor under the primary data items. This decision was made because the agency observed low out-of-compliance percentages for food sources in the previous 10-year study. Inspections conducted by regulatory partners substantiated these findings.

Table 3. Foodborne Illness Risk Factors and the Associated Primary Data Items Examined in the Study

Foodborne Illness Risk Factor	Associated Primary Data Item Numbers and Description
Poor Personal Hygiene	Data Item #1 – Employees practice proper handwashing. Data Item #2 – Employees do not contact RTE foods with bare hands.
Contaminated Equipment/ Protection from Contamination	Data Item #3 – Food is protected from cross contamination during storage, preparation, and display. Data Item #4 – Food contact surfaces are properly cleaned and sanitized.
Improper Holding Time/Temperature	Data Item #5 – Foods requiring refrigeration are held at the proper temperature. Data Item #6 – Foods displayed or stored hot are held at the proper temperature. Data Item #7 – Foods are cooled properly. Data Item #8 – Refrigerated, RTE foods are properly date marked and discarded within 7 days of preparation or opening.
Inadequate Cooking	Data Item #9 – Raw animal foods are cooked to required temperatures. Data Item #10 – Cooked foods are reheated to required temperatures.

Data Items, Information Statements, and Documenting Observations

Using the 2017 version of the FDA Food Code as the standard of measurement for compliance markings for observations of employee food safety behaviors/practices, the data collector marked observations and findings on the data collection form in four compliance categories (see Appendix A). The data collector determined whether observations of employee food safety practices or behaviors contained in the information statements were:

- **In Compliance (IN):** One or more information statements that are part of the data item were recorded as in compliance, and none of the information statements that are part of the data item was recorded as out-of-compliance.
- **Out-of-compliance (OUT):** One or more information statements that are part of the data item were recorded as out-of-compliance.

- **Not Observed (NO):** None of the information statements that are part of the data item was recorded as in compliance or out-of-compliance, and one or more information statements that are part of the data item were recorded as not observed. The “NO” marking was used when an information statement is a usual practice in the food establishment, but the data collector did not observe the practice during the data collection.

- **Not Applicable (NA):** All information statements that are part of the data item were recorded as not applicable. The “NA” marking was used when a data item or information statement was not a function of the food establishment.

Calculating Compliance Percentages for Food Safety Behaviors/Practices

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

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

Calculating Compliance Percentages for Each Risk Factor

Each risk factor category encompasses a number of different food safety practices that take place in delis, which include widely recognized, prevention-based practices. When these controls are utilized, they 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 delis out-of-compliance for each risk factor:

$$\frac{Total\ number\ of\ out-of-compliance\ observations\ for\ the\ data\ item}{Total\ number\ of\ observations\ (IN\ and\ OUT)for\ the\ data\ item} \times 100$$

Assessing Food Protection Manager Certification

Food protection managers have an important role in formulating policies, verifying that food employees carry out these policies, and communicating with these same employees to give information about recommended practices to reduce the risk of foodborne illness. (FDA, 2017). A Centers for Disease Control and Prevention Environmental Health Specialist-Network (EHS-Net) study suggests that the presence of a certified food protection manager reduces the risk for a foodborne outbreak for an establishment and was a distinguishing factor between restaurants that experienced a foodborne illness outbreak and those that had not (CDC, 2017). FDA's Retail Food Risk Factor Studies suggest that the presence of a certified manager has a positive correlation with more effective control of certain risk factors, such as poor personal hygiene, in different facility types (FDA, 2019a).

There are a number of state and local agencies that mandate food protection manager certification. It is appropriate for state and local agencies, by way of codes and ordinances or by policy to establish criteria for what types of permitted establishments could be exempt from the mandatory manager certification requirement and for determining the conditions under which the minimum number of certified food protection managers must be some number greater than one. Certification requirements of the Person in Charge vary across the nation (see Table 5). To ensure proper active managerial control, the Food Code requires that:

1. The Person in Charge be present at all times of operation.
2. The Person in Charge be a Certified Food Protection Manager.

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

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

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

- An American National Standards Institute (ANSI) National Accreditation Board (ANAB) accredited food protection manager certification program[2].
- A food protection manager certification program that was not ANSI-accredited, such as one that may have been developed and administered by the state or local regulatory authority with inspection oversight for the establishment.
- A source for which the establishment personnel could not provide documentation or specific reference.

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

[2] The American National Standards Institute (ANSI) National Accreditation Board (ANAB) 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 2017 FDA Food Code, §2-102.12, Certified Food Protection Manager

Assessing Food Safety Management Systems

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

- **Procedures (P):** A defined set of actions adopted by food service management for accomplishing a task in a way that minimizes food safety risks.

- **Training (T):** The process of management's informing employees of the food safety procedures within the establishment and teaching employees how to carry them out.

- **Monitoring (M):** Routine observations and measurements conducted to determine if food safety procedures are being followed and maintained.

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

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

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

- Describe the critical limits for (the specific risk factor procedure or practice) as they apply to the deli.

- 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.

- Identify specific employees that have been assigned the responsibility to correctly perform (the specific risk factor procedure or practice).

- 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 deli.

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

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

1. **Nonexistent:** No system in place or system haphazardly implemented (no defined structure or frequency for implementation).

2. **Underdeveloped:** System is in early development. Efforts are being made, but there are crucial gaps in completeness and/or consistency.

3. **Well-developed**: System is complete, consistent, and oral or a combination of oral and written. The preponderance of the management system is oral.

4. **Well-developed and Documented:** System is complete, consistent, and primarily written. The preponderance of the management system is written.

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

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

Table 4. Food Safety Management System Category by Score

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

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

Example: Poor Personal Hygiene

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

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

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

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

The cumulative PTM score for this deli is 2.5.

Quality Assurance

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

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

Statistical Analysis

Statistical analysis of the data was performed utilizing JMP©, Version 17. Statistical significance of individual variables was determined at $p < 0.05$ to understand the relative effect of each variable on the out-of-compliance status of data items. The data was also analyzed by running descriptive statistics to describe the sampled population. Correlation analysis was conducted to identify relationships between variables. The impact of the presence of a CFPM and/or FSMS on the out-of-compliance data items was tested using multiple regression analysis. For each significant result, the moderating effect of multiple-unit status and complexity of food preparation was tested using multi- factor analysis of variance (ANOVA).

RESULTS AND DISCUSSION

Descriptive Statistics

This study included 438 delis. Most delis were classified as risk category 2(41.3%) or 3(56.8%). The majority of delis (95.2%) were part of a multiple-unit operation. Almost 46% of delis had well-developed and well-developed and documented FSMS. In delis that were part of multiple-unit operations, 47.6% of establishments had well-developed or well-developed and documented FSMS, as compared to only 9.5% of single- unit establishments.

As shown in Table 5, more than half of the establishments in the present study had a person in charge that was a CFPM. Almost sixty percent of delis had a person in charge present at the time of data collection, whereas 26.7% had no CFPM employed at all.

Table 5. Descriptive Statistics

Characteristic	Number of Delis (N = 438)	%
Certified Food Protection Manager		
None	117	26.7%
Employed but not present	60	13.7%
Employed and present	11	2.5%
Person in charge	250	57.1%
Food Safety Management System*		
Nonexistent	27	6.2%
Underdeveloped	210	48.1%
Well-developed	159	36.4%
Well-developed and documented	41	9.4%
Risk Categorization		
Risk category 2	181	41.3%
Risk category 3	249	56.8%
Risk category 4	8	1.8%
Multiple-unit		
Yes	417	95.2%
No	21	4.8%

*1 NA or missing

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

Table 6. Jurisdictional Characteristics

Characteristic	Number of Delis	%
Jurisdiction enrolled in program standards		
Yes	340	77.6%
No	98	22.4%
Jurisdiction meets Standard 1		
Yes	109	32.1%
No	231	67.9%
Jurisdiction uses a grading system		
Yes	185	42.2%
No	253	57.8%
Jurisdiction requires public posting of inspection results		
Yes	338	77.2%
No	100	22.8%
Jurisdiction has mandatory certified food protection manager requirement		
Yes	333	76.0%
No	105	24.0%

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 were studied among 438 delis. Table 7 shows the percentage of delis found out-of-compliance for each risk factor. The two most commonly occurring risk factors found out-of-compliance were improper holding (84.0%) and poor personal hygiene (61.9%). Inadequate cooking was the least commonly occurring risk factor found out-of-compliance (9.3%). This risk factor (inadequate cooking) was observed in 78.5% of delis. 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 deli as part of its pre-opening procedures.

Table 7. Risk Factors Out-of-Compliance

Foodborne Illness Risk Factor	Delis (# OUT)	Total Obs. (IN & OUT)	% OUT
Poor Personal Hygiene	271	438	61.9%
Contaminated Equipment	231	438	52.7%
Improper Holding/Time and Temperature	368	438	84.0%
Inadequate Cooking	32	344	9.3%

Table 8 shows the percentage of delis found out-of-compliance for each of 10 primary data items. Employees do not contact ready-to-eat foods with bare hands was the least-occurring primary data item out-of-compliance.

The high out-of-compliance percentage of the improper holding risk factor in delis (84.0%) was largely due to high out-of-compliance findings in two of the four data items the risk factor includes: data items 5 (foods requiring refrigeration are held at proper temperature) and 7 (foods are cooled properly). These data items had out-of-compliance percentages of 58.9% and 41.9%, respectively.

The out-of-compliance finding with handwashing (data item 1, 61.9 %) was due to at least one observation in 55.7% of delis that an employee did not clean and wash their hands at the required time, and in 27.6% of delis that at least one employee was not properly cleaning and washing their hands.

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

Data Item	Description	Delis (# OUT)	Total Obs. (IN & OUT)	% OUT
1	Employees practice proper handwashing	271	438	61.9%
2	Employees do not contact ready-to-eat foods with bare hands	6	438	1.4%
3	Food is protected from cross contamination during storage, preparation, and display	136	438	31.1%
4	Food contact surfaces are properly cleaned and sanitized	172	438	39.3%
5	Foods requiring refrigeration are held at proper temperature	258	438	58.9%
6	Foods displayed or stored hot are held at proper temperature	173	393	44.0%
7	Foods are cooled properly	111	265	41.9%
8	Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening	156	436	35.8%
9	Raw animal foods are cooked to required temperatures	14	316	4.4%
10	Cooked foods are reheated to required temperatures	21	166	12.7%

Table 9 shows the percentage of delis found out-of-compliance for each of 10 primary data items in rank order according to compliance status.

Data items 2 (employees do not contact ready-to-eat foods with bare hands), 9 (raw animal foods are cooked to required temperatures), and data item 10 (Cooked foods are reheated to required temperatures) were found out-of-compliance least commonly at 1.4%, 4.4%, and 12.7% respectively. Data items 6 (Foods displayed or stored hot are held at proper temperature), 5 (foods requiring refrigeration are held at proper temperature) and 1 (employees practice proper handwashing) were found out-of-compliance most commonly at 44.0%, 58.9%, and 61.9%, respectively. This suggests that while delis are better at managing bare-hand contact with ready-to-eat foods and ensuring foods are cooked to required temperatures and reheated properly, they need to gain better control over cold holding, hot holding, and employee handwashing.

The high out-of-compliance percentage of the improper holding risk factor in delis (Table 7, 84.0%) was largely due to high out-of-compliance findings in two of the four data items the risk factor includes: data items 5 (foods requiring refrigeration are held at proper temperature) and 6 (foods displayed or stored hot are held at proper temperature) (foods are cooled properly). These data items had out-of-compliance percentages of 58.9% and 44%, respectively.

The out-of-compliance finding with handwashing (data item 1, 61.9 %) (Table 9) was due to at least one observation in 55.7% of delis that an employee did not wash their hands at the required time, and in 27.6% of delis that at least one employee was not properly washing their hands.

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

Data Item	Description	Delis (# OUT)	Total Obs. (IN & OUT)	% OUT
1	Employees practice proper handwashing	271	438	61.9%
5	Foods requiring refrigeration are held at proper temperature	258	438	58.9%
6	Foods displayed or stored hot are held at proper temperature	173	393	44.0%
7	Foods are cooled properly	111	265	41.9%
4	Food contact surfaces are properly cleaned and sanitized	172	438	39.3%
8	Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening	156	436	35.8%
3	Food is protected from cross contamination during storage, preparation, and display	136	438	31.1%
10	Cooked foods are reheated to required temperatures	21	166	12.7%
9	Raw animal foods are cooked to required temperatures	14	316	4.4%
2	Employees do not contact ready-to-eat foods with bare hands	6	438	1.4%

Number of Data Items Out-of-Compliance per Deli

Table 10 lists the cumulative number of delis that are found out-of-compliance by the number of data items. The tables also display the corresponding percentage, and cumulative percentages.

- Median number of primary data items out-of-compliance = 3.
- 62.1% of delis (272) had 3 or fewer primary data items out-of-compliance.
- 8.4% of delis (37) had no primary data items out-of-compliance.
- 12.8% of delis (56) had one primary data item out-of-compliance.

Table 10. Overall Number of Primary Data Items Out-of-Compliance Percentile

Number of Primary Data Items Out-of-Compliance	Number of Delis	%	Cumulative Number of Delis	Cumulative %
0	37	8.4%	37	8.4%
1	56	12.8%	93	21.2%
2	90	20.5%	183	41.8%
3	89	20.3%	272	62.1%
4	69	15.8%	341	77.9%
5	60	13.7%	401	91.6%
6	23	5.3%	424	96.8%
7	11	2.5%	435	99.3%
8	3	0.7%	438	100.0%
9	0	0.0%	438	100.0%
10	0	0.0%	438	100.0%

Multiple-unit Operations

Delis that were part of a multiple-unit operation had significantly lower number of primary data items out-of-compliance ($p < 0.0001$) compared to those not part of a multiple-unit operation (Table 11). Delis part of an operation with two or more units were classified as multiple-unit operations.

Table 11. Mean Number of Primary Data Items Out-of-Compliance by Multiple-unit Operation Status

Multiple-unit	Number of delis	Mean Number of Primary Data Items Out-of-Compliance
No	21	4.76
Yes	417	2.92

Risk Categorization

Risk category 2 establishments had significantly lower primary data items out-of-compliance ($p < 0.05$) compared to risk category 3 and 4 establishments (Table 12).

Table 12. Mean Number of Primary Data Items Out-of-Compliance by Risk Category

Risk category	Number of delis	Mean Number of Primary Data Items Out-of-Compliance
2	181	2.26
3	249	3.53
4	8	3.63

Grading, Inspection Reporting, and Food Handler Training

Delis located in jurisdictions that graded establishments had significantly lower out-of-compliance ($p = 0.0213$) compared to those located in jurisdictions that did not grade (Table 13). Establishments located in jurisdictions where there was a requirement to make inspection results public had significantly lower out-of-compliance ($p = 0.0094$) than those without inspection reporting. Establishments in jurisdictions that required food handler training had significantly lower out-of-compliance ($p < 0.0001$) than establishments in jurisdictions that did not require food handler training.

Table 13. Mean Number of Primary Data Items Out-of-Compliance by Jurisdiction Variable

Variable	Number of delis	Mean Number of Primary Data Items Out-of-Compliance
Grading		
No	253	3.16
Yes	185	2.81
Inspection Reporting		
No	100	3.38
Yes	338	2.90
Food Handler Training Requirement		
No	334	3.19
Yes	104	2.42

Certified Food Protection Managers

As indicated in Table 14, delis with no CFPM employed averaged 3.63 primary data items out-of-compliance. Those with a CFPM employed at the delis but not present during data collection had an average of 2.92 primary data items out-of-compliance. The difference is significant ($p = 0.0054$). Those establishments with a CFPM present at the time of data collection had an average of 3.45 primary data items out-of-compliance. The average number out-of-compliance was not significantly different from those establishments with no CFPM employed ($p = 0.3744$). Delis with a CFPM present and in charge had an average of 2.72 primary data items OUT of compliance which was significantly lower than those with no certified manager ($p < 0 .0001$). Only 11 establishments were observed with a CFPM employed and present but not in charge.

Table 14. Mean Number of Primary Data Items Out-of-Compliance by Certified Food Protection Manager Status

Certified Manager Employed	Certified Manager Present	Certified Person in Charge	Number of delis	Mean Number of Primary Data Items Out-of-Compliance
No	No	No	117	3.63
Yes	No	No	60	2.92
Yes	Yes	No	11	3.45
Yes	Yes	Yes	250	2.72

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 Poisson regression model showed that the predictors, as a group, significantly influenced the number of primary data items out-of-compliance (Chi-square = 130.02, $p < .0001$). Table 15 presents the results of the effects tests, which test whether each predictor has a significant impact on out-of-compliance data items.

Table 15. Effects Tests

Variable	Number of Parameters	Degrees of Freedom (df)	Wald Chi-Square	P-value
Multiple unit	1	1	2.84	0.0917
Risk category	2	2	41.03	<.0001*
CFPM**	3	3	3.86	0.2767
FSMS***	1	1	42.33	<.0001*

*$p < 0.05$.
**CFPM treated as categorical variable, none, employed but not present, present, PIC.
***FSMS Treated as continuous variable, possible values from 1-4.

Table 16a and 16b present the least square means. These least squares means are on the log scale, representing the log of the expected rate for each level, adjusted for FSMS (mean 2.67) and the other categorical variables. These averages are adjusted to account for the average food safety management system score (FSMS = 2.67) and balance the effects of other factors, giving us a fair comparison across categories. The table shows the average log-rate of incidents for each category, with a measure of uncertainty (standard error).

Table 16a. Least Squares Means Log Scale

Factor	Level	LS Mean (Log Units)	Standard Error	95% Confidence Interval (Log Units)
Multiple-Unit	No	1.35	0.12	[1.11, 1.59]
	Yes	1.16	0.08	[1.01, 1.31]
Risk Categorization	2	0.96	0.08	[0.80, 1.12]
	3	1.35	0.07	[1.20, 1.49]
	4	1.45	0.19	[1.08, 1.83]
CFPM	None	1.26	0.08	[1.09, 1.42]
	Employed	1.23	0.11	[1.03, 1.44]
	Present	1.37	0.18	[1.02, 1.73]
	PIC	1.15	0.08	[0.99, 1.31]

The table below converts the values into the original units.

Table 16b. Least Squares Means conversion to original units.

Factor	Level	LS Mean (Log Units)	Expected rate (Original Units)	95% Confidence Interval (Original units)
Multiple-Unit	No	1.35	3.86	[3.03, 4.91]
	Yes	1.16	3.19	[2.73, 3.73]
Risk Categorization	2	0.96	2.62	[2.24, 3.07]
	3	1.35	3.85	[3.33, 4.46]
	4	1.45	4.28	[2.93, 6.26]
CFPM	None	1.26	3.52	[2.98, 4.14]
	Employed	1.23	3.43	[2.79, 4.23]
	Present	1.37	3.95	[2.77, 5.63]
	PIC	1.15	3.17	[2.70, 3.72]

The average number of out-of-compliance data items were examined, cases where facilities failed to meet food safety standards across different risk categories, management types, and whether a facility is part of a multi-unit operation. After adjusting for the food safety management system score (FSMS, averaged at 2.67) and balancing the effects of the other factors in the model, we found that facilities in Risk Category 2 have the fewest issues, averaging 2.6 out-of-compliance items, while those in Category 3 average 3.9, and Category 4 averages 4.3, showing a clear increase with higher risk levels. For management types, facilities with a manager present average 4.0 issues, compared to 3.5 for those with no manager, 3.4 for an employed but not present manager, and 3.2 for those with a Person in Charge (PIC). Facilities that are not part of a multi-unit operation average 3.9 issues, slightly more than the 3.2 for multi-unit facilities. These averages can vary by about 20-30%; for example, Risk Category 2's average of 2.6 could range from 2.2 to 3.1.

The main takeaway is that higher risk categories are linked to more compliance issues, with Risk Category 4 facilities having over 60% more out-of-compliance items than those in Risk Category 2. Management type and multi-unit status show smaller differences, with facilities having a manager present or not being part of a multi-unit operation tending to have slightly more issues, though these differences are less pronounced. This suggests that focusing on improving practices in higher-risk facilities could significantly reduce non-compliance, while the type of management or multi-unit status plays a smaller role.

Table 17 presents the results of the regression analysis. FSMS (Estimate = -0.22, Wald Chi-square = 42.33, $p < .0001$) was found to be a significant predictor and negatively related to out-of-compliance data items. This means that facilities with stronger food safety management systems (higher FSMS scores) tend to have fewer out-of-compliance data items.

Table 17. Parameter Estimates from Poisson Regression

Predicting Variable	*Estimate*	Standard Error	Wald	*P*
Multiple-unit: (No vs. Yes)	0.19	0.11	2.84	0.0917
Risk category (3 vs. 2)	0.38	0.06	39.62	<.0001*
Risk category (4 vs. 3)	0.11	0.19	0.29	0.5875
CFPM: (None vs. PIC)	0.10	0.07	2.47	0.1159
CFPM: (Employed vs. PIC)	0.08	0.09	0.85	0.3559
CFPM: (Present vs. PIC)	0.22	0.17	1.74	0.1875
FSMS	-0.22	0.03	42.33	<.0001*

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

FSMS (Continuous Outcome Variable)

Coefficient: -0.21591 ($p < 0.0001$)

Interpretation:

- For each one-unit increase in FSMS, the log of the expected response count decreases by 0.21591.
- Converting back to the original units, this corresponds to a 19.4% decrease in the expected response count for each one-unit increase in FSMS.
- For example, if a facility improves its FSMS score from 1 to 2, it would be expected that about 19% fewer out-of-compliance data items, assuming all other factors stay the same.

Risk Categorization [3 vs.2] was a significant pairwise comparison ($p < 0.0001$), with an estimate of 0.3849329. The interpretation of risk categorization in the original units.

Risk Categorization [3 vs. 2] (0.38):

- Rate Ratio = $e^{0.3849329} \approx 1.47$.
- 95% CI = $[e^{0.2650763}, e^{0.5047894}] \approx [1.30,1.66]$.
- When facilities in Risk Category 3 are compared to those in Risk Category 2, Category 3 has about 47% more out-of-compliance data items on average. The increase is approximately between 30% and 66% at a 95% confidence level.

Risk Categorization [4 vs.3] (0.11):

- Rate Ratio = $e^{0.1048959} \approx 1.11$.
- 95% CI = $[e^{-0.274128}, e^{0.4839199}] \approx [0.76,1.62]$.
- p-value = 0.5875 (not significant).
- Moving from Risk Category 3 to 4 shows only an 11% increase in incidents, but this difference could be due to chance.

Other Pairwise Comparisons (e.g., CFPM levels, Multiple-Unit):

- None of the CFPM or Multi-Unit comparisons were significant (all $p > 0.05$).

Overview of Average Incidents

When looking at the average data items out-of-compliance based on risk category, manager status, and multi-unit operation, after adjusting for food safety management systems (measured by FSMS, averaged at 2.67) and balancing the effects of the other factors in the model, we found:

- Risk Category 2 has about 2.6 data items out-of-compliance on average.
- Risk Category 3 jumps to about 3.9 incidents.
- Risk Category 4 is around 4.3 incidents.
- For certified manager status, having no manager ('None') averages 3.5 incidents, 'Employed' is 3.4, 'Present' is 4.0, and 'PIC' (the reference) is 3.2.
- Facilities not part of a multi-unit operation average 3.9 incidents, while those that are average 3.2.

What the Comparisons Mean:

When we looked at the different risk categories, we noticed a big increase in out-of-compliance observations from Category 2 to Category 3, with almost 47% more issues—think of it as nearly half again as many violations. The jump from Category 3 to Category 4 was much smaller, only about 11% more, and that difference might be due to chance. As for the type of management or whether a facility is part of a multi-unit operation, the differences in the number of out-of-compliance observations were tiny and could also be due to chance, so we don't have solid evidence that these factors have a material difference in the amount out-of-compliance data items.

To sum up the comparisons, moving from risk category 2 to risk category 3 showed a statistically significant difference in the number of primary data items out-of-compliance. Moving from risk category 3 to risk category 4, the certified manager status, and the multiple unit status did not have statistically significant differences for supplemental statistical analyses, please refer to Appendix E: Supplemental Statistical Analysis.

CONCLUSION

The purpose of this second deli data collection during the 2019-2022 study was to investigate the relationship between FSMS, CFPM, and the occurrence of risk factors and food safety behaviors/ practices commonly associated with foodborne illness in delis.

Key findings included:

- 76.0% of the delis in this study operated in jurisdictions that required a CFPM be employed, present, or the Person in Charge. Of the delis included in this study, 73.3% had a CFPM in some capacity.
- Delis that had a CFPM who was the person in charge at the time of the data collection had significantly better FSMS scores than those delis that did not have a CFPM present or employed.
- Delis with a CFPM who was 1) the person in charge and 2) present at the time of the data collection and had an average FSMS score of 2.87 while the average score for delis with no CFPM employed was 2.27. This indicates that having a CFPM present and in charge at all hours of operation enhances food safety management systems and reduces the number of out-of-compliance food safety behaviors/practice.
- Of the foodborne illness risk factors investigated in this study, delis had the best control over inadequate cooking. There remains a need to gain better control over improper holding/time and temperature and poor personal hygiene.

    - Of the food safety behaviors/practices investigated in this study, delis had the best control over the following:

        - Ensuring no bare-hand contact with RTE foods

        - Cooking raw animal foods to their required temperatures

    - There remains a need to gain better control over the following food safety behaviors and practices:

        - Employee handwashing (includes both when to wash and how to wash properly)

        - Foods displayed or stored hot are held at proper temperature

        - Foods requiring refrigeration are held at proper temperature

    - FSMS were the strongest predictor of data items being out-of-compliance: those with well-developed food safety management systems had significantly fewer food safety behaviors/practices out-of-compliance than did than did those with "less developed" food safety management systems. For example, delis with non-existent FSMS averaged 4.37 data items out-of-compliance, while delis with well-developed and documented FSMS averaged 1.95 data items out-of-compliance.

Areas of Future Study

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

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

APPENDICES

Appendix A: FDA Foodborne Illness Risk Factor Study Data Collection Tools

The following tools utilized in this study can be accessed online on FDA's retail food risk factor study webpage.

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

Deli Data Collection Form

Marking Instructions for the Data Collection Form

Appendix B: Data Collection Introduction Letter

Dear Owner/Manager:

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

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

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

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

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

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

FDA's previous research studies can be accessed and downloaded from the following web link: https://www.fda.gov/retailfoodriskfactorstudy

Public Reporting burden of this collection of information is estimated to average 90 minutes per response. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850. PRAStaff@fda.hhs.gov. OMB Control #0910-0799. Expires September 30, 2024

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

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

Sincerely,

[Data collector's contact information]

Appendix C: Limitations

Field Operations

Delis are dynamic. There is no set pattern of operation within a deli that will ensure all food safety practices and employee behaviors covered in this study will be observed by a data collector. Establishment type, the season of the year, the time of day, and the length of time available for each data collection are some of the factors that impacted direct observations of food safety practices within a deli. 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 deli as part of its pre-opening procedures. The timing of the data collection visit and the availability of cooked foods reheating to required temperatures are elements that influenced the data collector's ability to observe this data item.

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

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

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

Study Design

Sample Design

Twenty-six FDA data collectors conducted the data collections at delis. The data collectors were geographically dispersed throughout the United States. The geographic distribution of data collectors throughout the U.S. allows for a broad sampling of establishments in all regions of the U.S.; therefore, establishments were randomly selected to participate in the study from among all eligible establishments located within a 175-mile radius of each data collector's home location.

The total number of establishments in the country was approximately 78,919 and the total number within the sampling zones was 55,275. Roughly 70% of all establishments in the deli 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 deli data are part of ESRI's USA Business Locations and Business Summary. This dataset is updated annually, with the latest version updated in 2019. 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.

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

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

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

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

Comparing Data over Time

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

- Sample variations
- Changes in industry practices

Sampling Variations

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

The FDA tracked the actual time spent to complete data collection at each deli. The average time to complete data collection in delis was 101.26 minutes. Travel time to and from the deli 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 Delis

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

The first deli data collection period began in November 2015 and was completed in September 2016. This report highlights the statistically significant findings from the second deli data collection period from October 2019 through December 2022. Table 18 provides a summary of the 10-year study time frames for the deli data collection periods.

Table 18. Summary of Data Collection Time Frames for Delis

Industry	Facility Type	Initial Data Collection Period (Baseline Measurement)	2ND Data Collection Period	3RD Data Collection Period
Retail Food Store	Deli Department	Oct 1, 2015 to Dec 31, 2016	Oct 1, 2019 to Dec 31, 2022	Oct 1, 2026 to Sep 30, 2027

Appendix E: Supplemental Statistical Analysis

The Surveillance and Data Integration Division analyzed the data utilizing a main effects multi-factor analysis. Findings concluded that the primary variable associated with improved compliance was FSMS. The establishments' risk categorization was also predictive of the out-of-compliance rate. Establishments in jurisdictions that were not enrolled in the program standards had a lower percentage of out-of-compliance data items.

Reasons for performing the regression analysis:

Many factors were measured in the study, and several have statistically significant ($p < 0.05$) pairwise correlations with each other as seen in Table 19. The purpose of the analysis is to determine whether a factor has remaining or additional explanatory power or association with the response of interest, in this case compliance status, when other predictor variables are also included in the model. The goal is to identify potentially spurious correlations. In our regression analysis, we want to determine which variables were predictive of improved compliance when the set of correlated predictors were in the model. If a pairwise correlation becomes non-significant in the model, we state the pair-wise correlation was explained by other predictors and may be spurious.

Parameter Analysis

There are several variables that may affect the response variable "number of primary data items out of compliance." The multi-factor analysis model was run in JMP, Version 17, with all the variables. Then, each variable was removed from the full model to assess the effect on the change in model Generalized R-Square upon removal, presented in Table 19. The Generalized R-Square, as reported by JMP, is a measure of how well the model fits the data. A higher Generalized R-Square means the model does a better job of capturing patterns (variation) in the number of out-of-compliance data items. If there was minimal change in the Generalized R-Square upon removal of a predictor, it meant that the predictor's effect could be explained by other variables in the model. If there was a significant reduction in the Generalized R-Square upon removal, it indicated that the predictor in question had a meaningful impact on the model's fit that is not explained by the other variables. The percentage reduction in Generalized R-Square shows how much worse the model fits the data when a predictor is removed. A larger percentage means the predictor is more important for explaining non-compliance. We also reported the p-values of the Wald Chi-Square statistic, which JMP uses to test the significance of each predictor. The p-value from the Wald Chi-Square test tells us whether a predictor has a meaningful effect on the number of out-of-compliance data items. P-values greater than 0.05 were not generally considered to be statistically significant, meaning the predictor's effect might be due to chance. P-values less than 0.05 are bolded in Table19 and considered significant, meaning we're confident the predictor makes a difference.

Table 19. Parameter Analysis

	Model R-square	Reduction in R-square	% R-square reduction	Prob > Chi-Square
Model with all parameters	0.2736	NA	NA	NA
Management systems (FSMS)	0.1984	0.0752	27.49%	**<0.0001**
Risk Categorization	0.2237	0.0498	18.22%	**<0.0001**
Enrolled in program standards	0.2629	0.0107	3.91%	**0.0216**
Multiple-Unit	0.2690	0.0045	1.66%	0.0929
Certified manager (CFPM)	0.2677	0.0059	2.15%	0.3079
Requires food handler	0.2659	0.0077	2.82%	0.3462
Requires grading	0.2726	0.0010	0.36%	0.4391
Requires reporting	0.2735	0.0000	0.02%	0.8686
Requires CFPM	0.2736	0.0000	0.01%	0.9049

Note: FSMS (Food Safety Management System) is a continuous score from 1 to 4. Risk Categorization is an ordinal variable with levels 2, 3, and 4 (higher numbers indicate higher risk). CFPM (Certified Food Protection Manager) is categorical with levels none, employed but not present, present, and PIC. Multiple-Unit indicates whether the facility is part of a larger chain (Yes) or independent (No). "Enrolled in program standards" refers to participation in a specific food safety program. "Requires food handler," "Requires grading," "Requires reporting," and "Requires CFPM" indicate whether the facility is subject to these regulatory requirements.

Summary of Findings:

Table 19 shows that the Food Safety Management System (FSMS) and Risk Categorization are the most important predictors of out-of-compliance data items. Removing FSMS reduces the model's fit by 27.5%, and removing Risk Categorization reduces it by 18.2%, both with strong statistical significance ($p < 0.0001$). This means these two factors play a big role in explaining why some facilities have more non-compliance issues. Being enrolled in program standards also has a small but significant effect ($p = 0.0216$), reducing the model's fit by 3.9% (Note: facilities located in jurisdictions that are not enrolled in the program standards have lower out-of-compliance). Other factors, like whether a facility is part of a multi-unit operation or has a certified manager, don't seem to add much unique information to the model, as their removal has little impact on the fit ($p > 0.05$). The full model has a Generalized R-Square of about 0.27, meaning it captures about 27% of the patterns (variation) in the data. This value is typical for models of this type, as they often don't capture as much of the patterns (variation) as models for other kinds of data, but it suggests there may be other factors we haven't measured that also affect non-compliance.

Relationship between CFPM and FSMS

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

There is a relationship between the CFPM status and the FSMS. For example, facilities that had a CFPM (who is the PIC) at the time of inspection had a far higher percentage of well-developed or well-developed and documented FSMS than those that had no CFPM employed. Facilities that had a CFPM present who was also the PIC accounted for a majority of the deli establishments with well-developed or well-developed and documented FSMS. If an establishment had no CFPM employed, it was more likely to have an underdeveloped or non-existent FSMS. Establishments with a CFPM who was the PIC were more likely to have well-developed or well-developed and documented FSMS. These data are presented in Table 20.

Table 20. Certified Manager Status by Food Safety Management System

Certified Manager	FSMS Category Non-Existent (Number of delis)	FSMS Category Underdeveloped (Number of delis)	FSMS Category Well-Developed (Number of delis)	FSMS Category Well-Developed and Documented (Number of delis)
None	11.1% (13)	61.5% (72)	19.7% (23)	7.7% (9)
Employed	5.0% (3)	51.7% (31)	35.0% (21)	8.3% (5)
Present	0.0% (0)	36.4% (4)	63.6% (7)	0.0% (0)
PIC	4.4% (11)	41.4% (103)	43.4% (108)	10.8% (27)

Analysis of Least Squares Means Used in the Regression Analysis

The multiple-unit effect can be seen when the least squares means are analyzed (Table 21a and 21b). There was a not significant difference (p = 0.917) in the number of primary data items out-of-compliance depending upon the delis status as a multiple-unit operation. The least squares means were not significantly different for any level of CFPM. The risk category was significant. Establishments that were risk category 2 had significantly lower OUT of compliance than risk category 3 or 4.

Table 21a. Least Squares Means Log Scale

Factor	Level	LS Mean (Log Units)	Standard Error	95% Confidence Interval (Log Units)
Multiple-Unit	No	1.35	0.12	[1.11, 1.59]
	Yes	1.16	0.08	[1.01, 1.31]
Risk Categorization	2	0.96	0.08	[0.80, 1.12]
	3	1.35	0.07	[1.20, 1.49]
	4	1.45	0.19	[1.08, 1.83]
CFPM	None	1.26	0.08	[1.09, 1.42]
	Employed	1.23	0.11	[1.03, 1.44]
	Present	1.37	0.18	[1.02, 1.73]
	PIC	1.15	0.08	[0.99, 1.31]

Table 21b. Least Squares Means Conversion to Original Units

Factor	Level	LS Mean (Log Units)	Expected rate (Original Units)	95% Confidence Interval (Original units)
Multiple-Unit	No	1.35	3.86	[3.03, 4.91]
	Yes	1.16	3.19	[2.73, 3.73]
Risk Categorization	2	0.96	2.62	[2.24, 3.07]
	3	1.35	3.85	[3.33, 4.46]
	4	1.45	4.28	[2.93, 6.26]
CFPM	None	1.26	3.52	[2.98, 4.14]
	Employed	1.23	3.43	[2.79, 4.23]
	Present	1.37	3.95	[2.77, 5.63]
	PIC	1.15	3.17	[2.70, 3.72]

The numbers in the table (like the averages and their ranges) come from a Poisson regression model, which is used because we're counting things—like the number of out-of-compliance data items. The uncertainty around these averages, shown as standard errors and confidence intervals, is a bit different from what you'd see in a simpler model for things like heights or weights. In those simpler models, the uncertainty adds or subtracts a fixed amount, like saying an average height is 5 feet, plus or minus 1 inch. But in our model, the uncertainty works on a percentage basis because we're dealing with counts. For example, for Risk Category 2, the average number of out-of-compliance items is 2.6, and the range of uncertainty (95% confidence interval) is 2.2 to 3.1. This range isn't perfectly balanced around 2.6—it stretches a bit more on the higher side—because the uncertainty grows as the count gets larger, which is a natural feature of counting data. So, when we talk about how much these averages might vary, we're thinking in terms of percentages rather than fixed amounts.

This difference means we need to be careful when comparing averages. For instance, Risk Category 4 has a higher average (4.3) and a wider range of uncertainty (2.9 to 6.3) because its standard error is larger, reflecting more variability in higher counts. In simpler terms, the uncertainty in our results tells us how much the average number of issues might shift up or down, but that shift is bigger in percentage terms for larger averages, which is why the ranges look a bit uneven compared to what you might expect from other types of data.

The plot of mean primary data items out-of-compliance by FSMS score and CFPM status, shown in Figure 2, shows the relationship between FSMS, CFPM status, and compliance. The primary data items out-of-compliance decreases as the FSMS improve. Most establishments in the study had CFPM who were also the PIC at the time of data collection. These are represented in orange and contain the most area in the plot. Most of the establishments that had well-developed or well-developed and documented management systems had a CFPM who was also the PIC at the time of data collection.

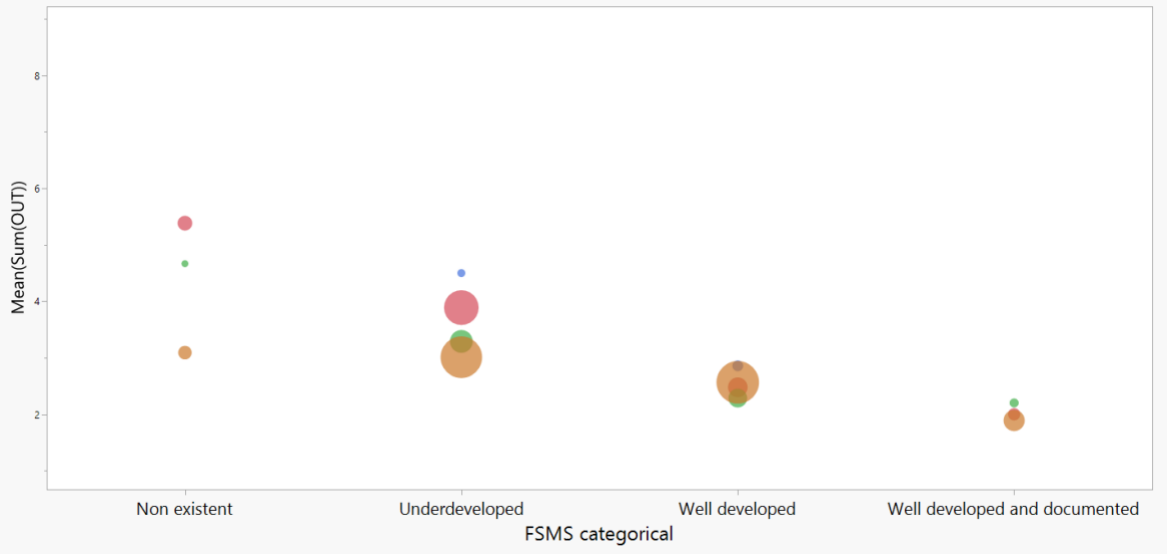


Figure 2 Plot of Mean Primary Data Items Out-of-Compliance by Food Safety Management System Category Deli

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