FDA U.S. FOOD & DRUG ADMINISTRATION

NATIONAL RETAIL FOOD TEAM

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

2015-2016

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Industry

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

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ACRONYMS/ABBREVIATIONS

Acronym	Meaning
AMC	Active Managerial Control
ANOVA	Analysis of Variance
ANSI	American National Standards Institute
BRC	British Retail Consortium
CDC	Centers for Disease Control and Prevention
CFPM	Certified Food Protection Manager
CFSAN	Center for Food Safety and Applied Nutrition
ESRI	Environmental Systems Research Institute
FDA	U.S. Food and Drug Administration
FSMS	Food Safety Management System
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Points
NA	Not Applicable
NO	Not Observed
SQF	Safe Quality Food Institute
TCS	Time/Temperature Control for Safety Food
PTM	Procedures, Training, and Monitoring
VNRFRPS	Voluntary National Retail Food Regulatory Program Standards

ABSTRACT

This report includes the background, design, and results of data collection on the occurrence of foodborne illness risk factors in the United States in retail food store deli departments (hereafter referred to as delis) during 2015-2016. It is a baseline 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 and food safety behaviors/practices in food service facilities. Data from the 2015-2016 collection will be used as a baseline 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.

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

BACKGROUND

Foodborne illness remains a major public health concern in the United States. Foodborne diseases cause approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths each year (Scallan et al., 2011). The annual economic burden from health losses due to foodborne illness is estimated at 77.7 billion dollars (Scharff, 2012).

Retail food stores employ 5 million workers and represent a combined annual sales volume of almost $800 billion (FMI, 2019). At the time of this data collection, there were approximately 152,741 retail food store establishments in the contiguous U.S. (ESRI, 2014).

According to the Centers for Disease Control and Prevention (CDC), when considering incidents in 2015 and 2016, retail food stores accounted for 23 outbreaks (3%), and 15 outbreaks (2%), respectively, and 572 illnesses (5%), and 239 illnesses (2%), respectively (CDC, 2015; CDC, 2016).

Foodborne Illness Risk Factors

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 to control the risks. These risk factors include:

- Poor personal hygiene
- Improper food holding/time and temperature

- Contaminated equipment/protection from contamination
- Inadequate cooking
- Food obtained from unsafe sources

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

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

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

Purpose of the Study

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

The objectives of this study are to:

- Identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in delis 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 delis differs based on an establishment's risk categorization and status as a single-unit or multiple-unit operation (e.g., delis located in retail food stores that are part of an operation with two or more units).

FSMS refers to a specific set of actions used by food service establishments to help achieve Active Managerial Control (AMC). 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 (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). 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 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 food safety knowledge and inspection scores (Cates et al., 2008; Brown et al., 2014).

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

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

Deli Data Collection

This report describes the data collected in delis in 2015-2016. Data from the 2015-2016 collection will be used as a baseline to assess trends in the occurrence of risk factors during data collections in 2019 and 2023. Data collection will occur in delis in 2015, 2019, and 2023. Additional information can be found in Appendix D of this report.

Deli Departments and Listeria Monocytogenes

Due to its prevalence in delis, FDA and others have studied *L. monocytogenes* in the retail environment for many years (Lubran, 2010; Maitland, 2013; Pouillot, 2015; Simmons, 2014). The FDA conducted a *L. monocytogenes* risk assessment in 2003, a follow up interagency risk assessment in 2013, and a multi-year (2010-2013) interagency Listeria monocytogenes Market Basket Survey for selected refrigerated ready-to-eat foods purchased at retail food stores in the United States (Luchansky et. al., 2017).

The FDA's educational effort to raise the awareness of cleaning, sanitizing, and maintenance of deli slicers was launched in 2011 with educational materials on "Sanitation Concerns with Commercial Deli Slicers". A recent study was conducted to ascertain the frequency with which retail delis met the recommendations in the FDA educational materials for Commercial Deli Slicers. The study found that approximately one quarter of the delis in the analysis met the FDA recommended slicer inspection frequency (Lipcsei et al., 2018).

Maitland et al. (2013) stated that the likelihood of contamination with *L. monocytogenes* is higher in deli meats sliced at the retail market than those products sliced and packaged at the processing plant. However, Luchansky et al. (2017) found that for deli meats (and five other products), the percentage of positive samples was significantly lower than that reported in the previous decade based on comparable surveys in the United States.

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. 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, 2013a). 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 (VNRFRPS)(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.

Deli Department Characteristics

In addition to local jurisdictional requirements with which retail food stores must comply, retail food stores themselves differ in complexity of food preparation and organizational structure. Including food preparation and organizational structure information for each retail food store in this data collection allows for assessing how the occurrence of food safety behaviors/practices in retail food stores differs based on complexity of food preparation and status as a single-unit or multiple-unit operation.

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.

Retail Food Store Selection

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 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, • Areas where meat and poultry products are cooked and offered for sale as ready-to-eat and are managed by the deli department manager.

Retail Food Store 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 150-mile radius from the home locations of the 22 FDA Retail Food Specialists performing the data collection. For this study, the complexity of food preparation was represented by the food establishment's risk categorization as found in Annex 5 of the 2013 FDA Food Code (see Table 2). This risk categorization was used to determine if an establishment was eligible for data collection. 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 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

Retail Food Specialists (data collectors) conducted site visits throughout the United States at randomly selected retail food stores to perform data collections. All data collectors 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 data collectors in applying and interpreting the FDA *Food Code*. In addition, all data collectors possessed technical expertise in retail food safety and a solid understanding of food service operations within delis.

Retail Food Store Selection

A Geographic Information System database containing a listing of U.S. businesses was used as the establishment inventory for the retail food store data collection. The total number of establishments in the country was approximately 67,160. Retail food stores 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 24 data collectors. The total number of establishments within the sampling zones was 42,159. As a result, roughly 63% of all establishments in the retail food store segment were eligible for selection. Figure 1 depicts the sample selection coverage area.

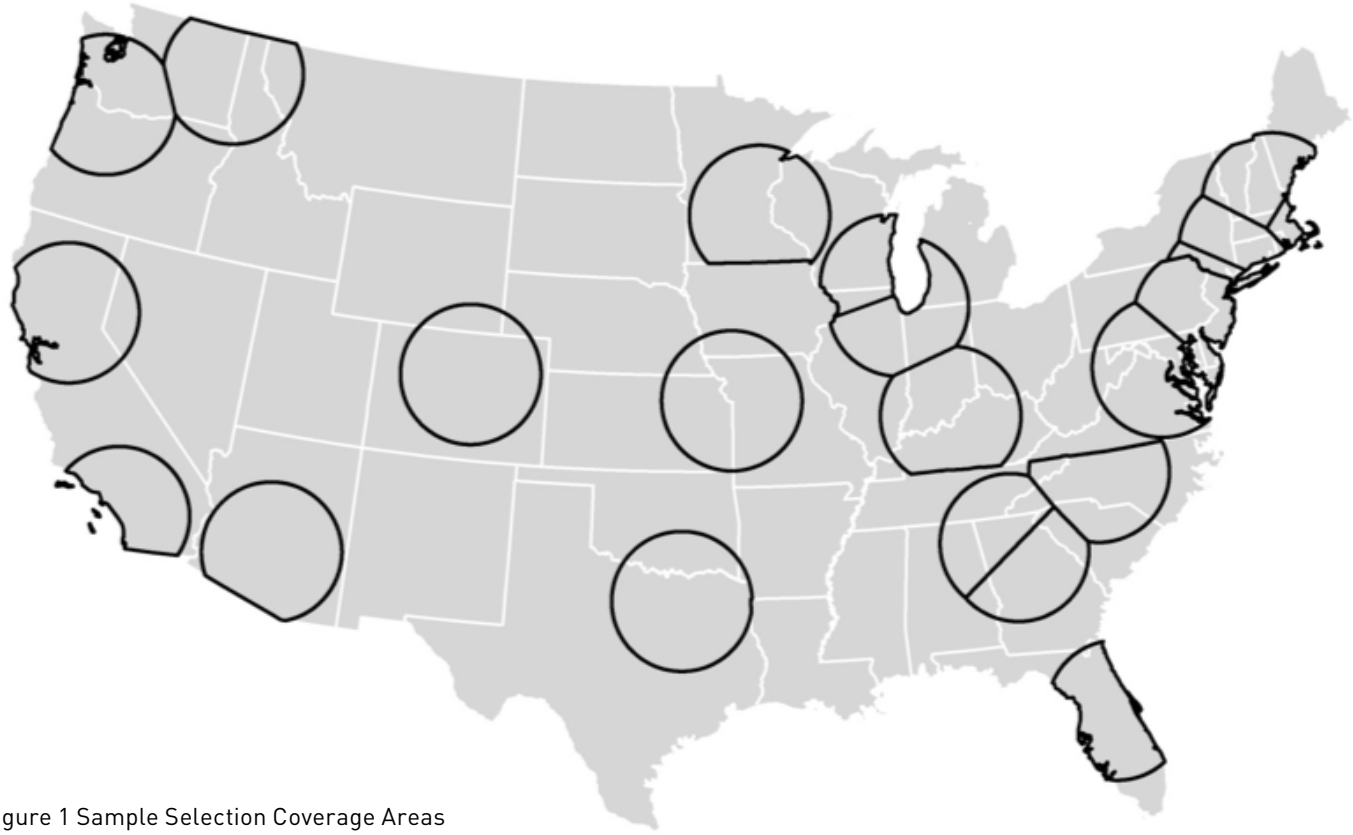

Figure 1 Sample Selection Coverage Areas

Sample Size

The FDA CFSAN Biostatistics Team determined that a minimum of 384 deli data collections was needed during the initial and subsequent data collection periods. This sample size provides a sufficient number of 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 397 data collections for deli departments.

The sample establishment inventory was distributed evenly among the data collection areas. 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 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 (2013-2024– 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 Retail Food Stores

The state or local jurisdictions with regulatory responsibility for conducting retail food inspections of the selected retail food stores were contacted prior to conducting a data collection at the establishment. Data collectors verified, through discussions with the regulatory authority, whether the retail food store was under any legal notice. If the selected retail food store 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 Retail Food Stores

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 VNRFRPS, 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 retail food stores 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 retail food store 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. 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 retail food store, data collection was not performed, and a substitute retail food store was randomly selected to replace the one that opted not to participate in the study.

The data collector 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 data collectors had a clear understanding of food processes and procedures. The owner or person in charge of the retail food store 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 (data items), 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, 2013a). Table 3 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 retail food stores. 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 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 ready-to-eat 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, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening.
Inadequate Cooking	• Data Item #9 – Raw animal foods are cooked to required temperatures. • Data Item #10 – Cooked foods are reheated to required temperatures.

Data Items, Information Statements, and Documenting Observations

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

- **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. 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 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 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 delis out-of-compliance for each risk factor:

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

Assessing Food Protection Manager Certification

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

- A CFPM was employed at the deli
- 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 deli personnel provided a "yes" response, the data collector made an attempt to verify the response by requesting to view a copy of the certificate. The data collector also noted whether the certification was obtained from:

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

In addition, by interviewing the person in charge, 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.

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

Assessing Food Safety Management Systems

While FSMS vary across the retail and food service industry, consistent components include procedures, training, and monitoring. For the purpose of this study, these three key elements were used to assess a deli department'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 deli 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 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 deli
- 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 deli

Based on management responses for each area described above, the data collector 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.

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 below:

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 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 department 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 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 13. 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 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).

Descriptive Statistics

This study included 397 deli departments:

- Most delis were classified as risk category 2 (48.4%) or 3 (46.6%).
- The majority of delis (74.1%) were part of a multiple-unit operation.
- Approximately 32% of delis had well-developed or well-developed and documented FSMS.

As shown in Table 5, more than half of the establishments in the study had a person in charge that was a CFPM, whereas 33.5% had no CFPM employed at all. Most delis operated in jurisdictions that used grading publicly posted inspection results and had a requirement that establishments must have a CFPM (Table 5).

Table 5 Descriptive Statistics

Characteristic	Number of Delis (N = 397)	Percentage
Certified Food Protection Manager		
None	133	33.5%
Employed but not present	56	14.1%
Employed and present	5	1.3%
Person in charge	203	51.1%
Food Safety Management System (5 NA or missing*)		
Nonexistent	48	12.2%
Underdeveloped	220	56.1%
Well-developed	101	25.8%
Well-developed and documented	23	5.9%
Risk Categorization		
Risk category 2	192	48.4%
Risk category 3	185	46.6%
Risk category 4	20	5.0%
Multiple-unit		
Yes	294	74.1%
No	103	25.9%

* The 5 NA or missing was due to data items randomly selected for the PTM evaluation not observed in the facility; therefore, a FSMS score could not be calculated. Additional data items were not assigned for evaluation of PTM if the first set of randomly selected data items could not be evaluated.

It is worth noting that the majority of the delis (73.8%) in this study operated in jurisdictions enrolled in the VNRFRPS, but the majority of those jurisdictions (74.7%) did not meet Program Standard 1, which applies to the regulatory foundation used by a retail food program (Table 6).

Table 6 Jurisdictional Characteristics

Characteristic	Number of Delis	Percentage
Jurisdiction enrolled in the VNRFRPS		
Yes	293	73.8%
No	104	26.2%
Jurisdiction meets Standard 1		
Yes	74	25.3%
No	219	74.7%
Jurisdiction uses a grading system		
Yes	204	51.4%
No	193	48.6%
Jurisdiction requires public posting of inspection results		
Yes	256	64.5%
No	141	35.5%
Jurisdiction has mandatory certified food protection manager requirement		
Yes	263	66.2%
No	134	33.8%
Jurisdiction requires food handler card		
Yes	133	33.5%
No	264	66.5%

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

Percent Out-of-Compliance

The occurrence of foodborne illness risk factors and associated food safety behaviors/practices were studied among 397 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 (91.2%) and poor personal hygiene (71.5%). Inadequate cooking had the lowest out-of-

compliance at 11.5%. This risk factor (inadequate cooking) was observed in 68.0% of delis. The timing of the data collection visit may have influenced the 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.

The high out-of-compliance percentage for the improper holding risk factor in deli departments (91.2%) was due primarily to high out-of-compliance rates for 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 70.0% and 62.9%, respectively (Table 7).

Table 7 Risk Factors Out-of-Compliance

Foodborne Illness Risk Factor	Delis (# OUT)	Total Obs. (IN & OUT)	% OUT
Poor Personal Hygiene	284	397	71.5%
Contaminated Equipment	248	397	62.5%
Improper Holding/Time and Temperature	362	397	91.2%
Inadequate Cooking	31	270	11.5%

Table 8 shows the percentage of delis found out-of-compliance for each of the 10 primary data items. Raw animal food cooked to required temperature was the least-occurring primary data item out-of-compliance.

There was a high out-of-compliance percentage for the handwashing risk factor in deli departments (72.1%). In 61.7% of delis there was at least one observation that an employee did not clean and wash their hands at the required time, and in 48.7% 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	284	394	72.1%
2	Employees do not contact ready-to-eat foods with bare hands	22	397	5.5%
3	Food is protected from cross contamination during storage, preparation, and display	171	397	43.1%
4	Food contact surfaces are properly cleaned and sanitized	190	397	47.9%
5	Foods requiring refrigeration are held at proper temperature	278	397	70.0%
6	Foods displayed or stored hot are held at proper temperature	177	334	53.0%
7	Foods are cooled properly	117	186	62.9%
8	Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening	203	389	52.2%
9	Raw animal foods are cooked to required temperatures	12	249	4.8%
10	Cooked foods are reheated to required temperatures	21	122	17.2%

As shown in Table 9, the data items found least commonly out-of-compliance were data items 9 (Raw animal foods are cooked to required temperatures), 2 (Employees do not contact ready-to-eat foods with bare hands), and data item 10 (Cooked foods are reheated to required temperatures). These data items had an out of compliance rate of 4.8%, 5.5%, and 17.2%, respectively. The data items found out-of-compliance most commonly were data items 7 (Foods are cooled properly), 5 (Foods requiring refrigeration are held at proper temperature), and 1 (Employees practice proper handwashing). These data items had an out-of-compliance rate of 62.9%, 70.0%, and 72.1%, 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, there remains a need to gain better control over cooling, cold holding of foods requiring refrigeration, and employee handwashing.

Table 9 Total Number and Percentage of Delis Out-of-Compliance for Each Data Item in Descending Order

Data Item	Description	Delis (# OUT)	Total Obs. (IN & OUT)	% OUT
1	Employees practice proper handwashing	284	394	72.1%
5	Foods requiring refrigeration are held at proper temperature	278	397	70.0%
7	Foods are cooled properly	117	186	62.9%
6	Foods displayed or stored hot are held at proper temperature	177	334	53.0%
8	Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening	203	389	52.2%
4	Food contact surfaces are properly cleaned and sanitized	190	397	47.9%
3	Food is protected from cross contamination during storage, preparation, and display	171	397	43.1%
10	Cooked foods are reheated to required temperatures	21	122	17.2%
2	Employees do not contact ready-to-eat foods with bare hands	22	397	5.5%
9	Raw animal foods are cooked to required temperatures	12	249	4.8%

Number of Data Items Out-of-compliance per Deli

Table 10 lists the cumulative number of delis found out-of-compliance by the number of data items. The table also displays the corresponding mean, percentage, and cumulative percentages. A summary of these data follows:

- Median number of primary data items out-of-compliance = 4
- 46.8% of delis (186) had 3 or fewer primary data items out-of-compliance.
- 2.5% of delis (10) had no primary data items out-of-compliance.
- 7.1% of delis (28) had 1 primary data item out-of-compliance.

Table 10 Overall Median Number of Primary Data Items Out-of-Compliance

Number of Primary Data Items Out-of-Compliance	Number of Delis	%	Cumulative Number of Delis	Cumulative %
0	10	2.5%	10	2.5%
1	28	7.1%	38	9.6%
2	72	18.1%	110	27.7%
3	76	19.1%	186	46.8%
4	80	20.2%	266	67.0%
5	61	15.4%	327	82.4%
6	49	12.3%	376	94.7%
7	14	3.5%	390	98.2%
8	5	1.3%	395	99.5%
9	2	0.5%	397	100.0%
10	0	0.0%	397	100.0%

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

A. Multiple-Unit Operations

Delis that were part of a multiple-unit operation had significantly lower number of primary data items out-of-compliance ($p < 0.05$) 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	103	4.2
Yes	294	3.6

B. 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 Status

Risk Category	Number of Delis	Mean Number of Primary Data Items Out-of-Compliance
2	192	3.3
3	185	4.1
4	20	4.5

C. Grading, Inspection Reporting, and Food Handler Training

Delis located in jurisdictions that graded establishments did not have significantly different results ($p > 0.05$) 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 did not have significantly different compliance ($p > 0.05$) than those without inspection reporting (Table 13). Establishments in jurisdictions that required food handler training had significantly lower number of data items out-of-compliance ($p < 0.05$) than establishments in jurisdictions that did not require food handler training (Table 13).

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	193	3.8
Yes	204	3.6
Inspection Reporting		
No	141	3.9
Yes	256	3.6
Food Handler Training Requirement		
No	264	3.9
Yes	133	3.4

D. Certified Food Protection Managers

Deli departments with no CFPM employed averaged 4.1 primary data items out-of-compliance (Table 14). Delis with a CFPM present who was also the PIC had an average of 3.4 primary data items out-of-compliance which was significantly lower than those with no CFPM present or no CFPM at all ($p < 0.05$).

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	133	4.1
Yes	No	No	56	4.1
Yes	Yes	No	5	3.8
Yes	Yes	Yes	203	3.4

Correlations

Table 15 presents correlations between different factors. FSMS were most highly correlated with a CFPM, number of risk factors out-of-compliance, multiple-unit status, and the number of primary data items out-of-compliance. The positive correlation with CFPM indicates that as the CFPM category increases (from no CFPM employed to the PIC being a CFPM), the FSMS category also increases (from non-existent to well-developed and documented).

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

Table 15 Correlations Between Study Variables

Row	Risk Factors Sum (OUT)	Primary Data Items Sum (OUT)	FSMS Score	Uses a Grading System	Program Includes Public Reporting	Mandatory Food Protection Manager	Establishment is Part of Multi-Unit	Enrolled Program Standards	Requires Food Handler Card	Certified Manager	Risk Category
Risk factors Sum(OUT)	1.0000										
Primary Data Items Sum(OUT)	0.8188	1.0000									
FSMS Score	-0.2743	-0.3619	1.0000								
Uses a Grading System	-0.0538	-0.0706	-0.0035	1.0000							
Program Includes Public Reporting	-0.0451	-0.0862	0.0648	0.5419	1.0000						
Mandatory Food Protection Manager	0.0258	0.0535	0.0895	0.2543	0.2049	1.0000					
Establishment is Part of Multi-Unit	-0.0924	-0.1496	0.4864	0.0911	0.1491	0.1487	1.0000				
Enrolled Program Standards	0.0809	0.0592	0.1735	-0.0064	0.1324	-0.0255	0.1179	1.0000			
Requires Food Handler Card	-0.0850	-0.1174	0.1003	0.4341	0.3818	0.0439	0.0549	0.1194	1.0000		
Certified Manager	-0.2152	-0.1877	0.3900	-0.0177	0.0562	0.2465	0.3213	0.0990	-0.0160	1.0000	
Risk Category	0.2148	0.2407	-0.0128	-0.1081	-0.1528	0.0991	0.0427	0.0286	-0.0034	-0.0328	1.0000

Regression:

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

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=13.6826, p < .0001). Table 16 presents the results of the effects tests, which tests the null hypothesis that all parameters associated with the effect are zero.

Table 16 Effects Tests

Variable	Number of Parameters	Degrees of Freedom (df)	Sum of Squares	F Ratio	Prob > F
Multiple-unit	1	1	0.1069	0.0410	0.8397
Risk category	2	2	68.4065	13.1044	<.0001*
CFPM	3	3	14.3949	1.8384	0.1397
FSMS	1	1	108.4748	41.5604	<.0001*

*p < 0.05

Table 17 presents the results of the regression analysis. FSMS (b = -0.7098, t (1) = -6.45, p < .0001) were found to be a significant predictor and negatively related to out-of-compliance data items. The negative parameter estimate for FSMS indicates that for every increase in the FSMS category, there is a reduction of 0.7098 in the number of primary data items out-of-compliance. CFPM and multiple-unit status were not significant predictors of out-of-compliance data items. Facilities that were risk category 2 had a significantly lower number of primary data items out-of-compliance compared to risk category 3 and 4 facilities.

Table 17 Regression Analysis

Predicting Variable	Estimate	Standard Error	t	P
Multiple-unit: No	-0.0222	0.1098	-0.20	0.8397
Risk category (3 – 2)	0.8048	0.1701	4.73	<.0001*
Risk category (4 – 3)	0.2789	0.3940	0.71	0.4795
CFPM: Employed	0.2621	0.2477	1.06	0.2907
CFPM: None	-0.1543	0.2306	-0.67	0.5037
CFPM: Present	0.1910	0.5484	0.35	0.7278
FSMS	-0.7098	0.1101	-6.45	<.0001*

*p < 0.05; Dependent Variable: Number of Data Items Out-of-compliance

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

CONCLUSION

The purpose of this first data collection in retail food store delis was to investigate the relationship between FSMS, CFPM, and the occurrence of risk factors and other food safety behaviors/practices commonly associated with foodborne illness.

Key findings included:

- 66.2% of the delis in this study operated in jurisdictions that required a CFPM but only slightly more than half of delis were found to have a CFPM employed and present at the time of data collection.
- Delis had the best control over the following food safety behaviors/practices:
  - Ensuring no bare-hand contact with ready-to-eat foods
  - Raw animal foods are cooked to required temperatures
- The top three food safety behaviors/practices needing better control were:
  - Employee handwashing (includes both when to wash and how to wash properly)
  - Foods requiring refrigeration are held at proper temperature
  - Foods are properly cooled
- FSMS were the strongest predictor of the compliance status of data items. As an establishment improved the development of its FSMS, the average number of primary data items out-of-compliance was reduced, resulting in reduced occurrence of foodborne illness risk factors.

  For example, delis with non-existent FSMS averaged 4.6 data items out-of-compliance, while delis with well-developed and documented FSMS averaged 2.4.
- Delis that had a CFPM who was also the person in charge at the time of data collection had significantly better FSMS scores than the delis that did not have a CFPM present or did not employ a CFPM at all.
- Delis that had a CFPM who was also the person in charge at the time of data collection had an average FSMS score of 2.6, while the average score for delis with no CFPM employed was 1.8. This suggests that having a CFPM who is also the PIC and present at all hours of operation enhances FSMS and the average number of primary data items out-of-compliance was reduced, resulting in reduced occurrence of foodborne illness risk factors.

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 deli departments and to determine cost-effective, evidence-based intervention strategies and inspection approaches for improving the nation's retail food protection system.

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

The following tools utilized in this study can be accessed online:

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:

https://www.fda.gov/media/98224/download

Retail Food Store Data Collection Form:

https://www.fda.gov/media/109676/download

Marking Instructions for the Data Collection Form:

https://www.fda.gov/media/98232/download

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 to 120 minutes. Approximately 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.

The 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, the 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, the 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.

The FDA's previous research studies can be accessed and downloaded from the following web link: https://www.fda.gov/food/retail-food-protection/retail-food-risk-factor-study.

Public Reporting burden of this collection of information is estimated to average 80 minutes per response for the person in charge of the deli department /operation within a retail food store. A 30-minute response is also included for the program director (or designated individual) of the regulatory authority. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., P150-400B, Rockville, MD 20850. PRAStaff@fda.hhs.gov. OMB Control #0910-0799. Expires September 30, 2021.

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 at [Data collector's phone number].

Sincerely

[Data collector's contact information]

APPENDIX C: LIMITATIONS

Field Operations

Retail food stores are dynamic. There is no set pattern of operation within a deli department 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 department. 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-two FDA data collectors conducted the data collections at retail food stores. The data collectors were geographically dispersed throughout the United States. The geographic distribution of data collectors throughout the U.S. allows for a broad sampling of establishments in all regions of the U.S.; therefore, establishments were randomly selected to participate in the study from among all eligible establishments located within a 150-mile radius of each data collector's home location.

The total number of establishments in the country was approximately 67,160 and the total number within the sampling zones was 42,159. Roughly 63% of all establishments in the retail food store 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 retail food store data are part of ESRI's USA Business Locations and Business Summary. This dataset is updated annually, with the latest version updated in July 2014. The data are stored as a GeoDataBase, which is a collection of geographic datasets of various types held in a common file system folder, a Microsoft Access database, or a multi-user relational database management system.

ESRI and its partner, Infogroup, reference several sources, including directory listings such as the *Yellow Pages* and business white pages; annual reports; 10Ks and Securities and Exchange Commission (SEC) information; federal, state, and municipal government data; business magazines; newsletters and newspapers; and information from the U.S. Postal Service. To ensure accurate and complete information, Infogroup conducts annual telephone verifications with each business listed in the database.

Retail food store addresses are geocoded to assign latitude and longitude coordinates to each retail food store 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. Retail food stores 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 deli departments 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 retail food stores. There is no statistical justification for examining reduced sets of results particular to, for example, two chains of retail food stores, 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 department. The average time to complete data collection in deli departments was 89.4 minutes. Travel time to and from the deli department 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 RETAIL FOOD STORES

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 initial deli department data collection period began in October 2015 and was completed in December 2016. This report highlights the statistically significant findings from that data collection period. Table 18 provides a summary of the 10-year study time frames for the deli department data collection periods.

Table 18 Summary of Data Collection Time Frames for Deli Departments

Industry Segment	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, 2020	Oct. 1, 2023 To Dec. 31, 2024

APPENDIX E: SUPPLEMENTAL STATISTICAL ANALYSIS

The Biostatistics and Bioinformatics Staff analyzed the data utilizing a main effects multi-factor ANOVA. Findings concluded that the primary variable associated with improved compliance was FSMS. In the analysis, the establishments' risk categorization and the regulatory authority's enrollment status in the VNRFRPS were also predictive of the out-of-compliance rate. Delis in jurisdictions that were not enrolled in the VNRFRPS had a lower percentage of out-of-compliance data items. There were statistically significant main effect P-values in the model for FSMS, risk category and enrolled in program standards.

Reasons for performing the regression analysis:

Many factors were measured in the study, and several have statistically significant ($p<0.05$) pairwise correlations with each other as seen in Tables 10-13. The purpose of the ANOVA is to determine whether a factor has remaining or additional explanatory power or association with the response of interest, in this case compliance status, when other predictor variables are also included in the model. The goal is to identify potentially spurious correlations. In our regression analysis, we want to determine which variables were predictive of improved compliance when the set of correlated predictors were in the model. If a pairwise correlation becomes non-significant in the ANOVA model, we state the pair-wise correlation was explained by other predictors and may be spurious.

Parameter analysis:

There are several variables that may affect the response variable "*number of primary data items out of compliance*". The multi-factor ANOVA model was run in JMP, Version 13 with all the variables. Then, each variable was removed from the full model in order to assess the effect on the change in model R-squared upon removal, presented in Table 19. The R-squared represents the amount of variance in the response variable that was explained by the model. If there was minimal change in the model R-square upon removal of a predictor, it meant that the correlation between the response and the variable could be explained by other variables in the model. If there was a significant reduction in R-squared upon removal, it indicated that the predictor in question had statistical explanatory power that is not explained by the other variables. We also reported the P-values of the F statistic. P-values greater than 0.05 were not generally considered to be statistically significant. P-values less than 0.05 are bolded in Table 19 and considered significant.

Table 19 Parameter Analysis

Delis	Model R- Square	Reduction in R- Square	% R-Square Reduction	Prob > F
Model with all parameters	0.238224			
Management systems (FSMS)	0.145662	0.092562	38.86%	<0.0001
Multiple-Unit	0.237836	0.000388	0.16%	0.6619
Risk category	0.200661	0.037563	15.77%	<0.0001
Certified Manager (CFPM)	0.225186	0.013038	5.47%	0.0941
Enrolled in program standards	0.224110	0.014114	5.92%	0.0087
Jurisdiction requires CFPM	0.233261	0.004963	2.08%	0.1184
Jurisdiction requires grading	0.237394	0.000830	0.35%	0.5225
Jurisdiction requires reporting	0.237775	0.000449	0.19%	0.6379
Jurisdiction requires food handler card	0.224308	0.013916	5.84%	0.1454

Removing only the FSMS variable from the model resulted in a reduction of R-square of 38.86%. Removing only the risk category variable resulted in a 15.77% reduction in R-squared. The removal of any of the other variables from the model had a much smaller effect on the R-square.

Removing both the FSMS and risk category variables resulted in a 54.63% reduction in R- squared.

The average primary data items out-of-compliance for establishments with nonexistent FSMS was 4.6, while those with well-developed and documented FSMS had 2.4 primary data items out-of-compliance. In this analysis, only the predictors of FSMS, risk category, and VNRFRPS enrollment had statistically significant effects on the model predictions, with both significant at the $p < 0.05$ level.

Effect of Certified Food Protection Manager (CFPM) on Food Safety Management Systems (FSMS):

It is important to note that the CFPM category does not have a statistically significant 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 (employed, present, or a CFPM who is 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 almost half of the 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 below.

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	24.0% (31)	63.6% (82)	11.6% (15)	0.8% (1)
Employed	5.4% (3)	58.9% (33)	25.0% (14)	10.7% (6)
Present	0.0% (0)	80.0% (4)	20.0% (1)	0.0% (0)
PIC	6.9% (14)	50.0% (101)	35.1% (71)	7.9% (16)

Analysis of Least Squares Means Used in the Regression Analysis

The multiple-unit effect can be seen when the least squares means are analyzed, presented in Table 21. There was no significant difference ($p > 0.05$) in the number of primary data items out-of-compliance depending upon the deli status as a multiple-unit operation. The least squares means were not significantly different for any level of CFPM. The risk category was significant ($p<.0001$). Establishments that were risk category 2 had significantly lower primary data items out-of-compliance.

Table 21 Least Squares Means

Variable	Least Squares Means	Standard Error
Multiple-unit		
No	3.4	0.2679
Yes	3.5	0.2176
Risk category		
2	3.4	0.2180
3	4.2	0.2264
4	4.5	0.4149
CFPM		
None	3.3	0.1754
Employed	3.7	0.2426
Present	3.6	0.7318
Person in charge	3.1	0.1581

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 FSMS Category

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