ICR ATTACHMENT A

U.S. Food and Drug Administration

Study on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2024)

Protocol for the Data Collection

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I. Background

In 1998, the U.S. Food and Drug Administration's (FDA) National Retail Food Team initiated a ten-year voluntary study to measure trends in the occurrence of foodborne illness risk factors - preparation practices and employee behaviors most commonly reported to the Centers for Disease Control and Prevention (CDC) as contributing factors to foodborne illness outbreaks at the retail level. Specifically, the study included data collection inspections of various types of retail and foodservice establishments at five-year intervals (1998, 2003, and 2008) in order to observe and document trends in the occurrence of the following foodborne illness risk factors:

- Food from Unsafe Sources
- Poor Personal Hygiene
- Inadequate Cooking
- Improper Holding/Time and Temperature
- Contaminated Equipment/Protection from Contamination

FDA developed reports summarizing the findings for each of the three data collection periods (1998, 2003, and 2008). Data from all three data collection periods were analyzed to detect trends in improvement or regression over time and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types.

The research obtained from these Studies provides FDA a solid foundation for developing a national retail food program model that can be used by federal, state, local, and tribal agencies to:

- Identify essential food safety program performance measurements;
- Assess strengths and gaps in the design, structure, and delivery of program services;
- Establish program priorities and intervention strategies focused on reducing the occurrence of foodborne illness risk factors; and
- Create a mechanism that justifies program resources and allocates them to program areas that will provide the most significant public health benefits.

II. 2013-2024 Study Objectives and Purpose

Using this ten-year study as a foundation, FDA has developed a new study design. The design of the new study will determine the following for each facility type included in the study:

- The foodborne illness risk factors that are in most need of priority attention during each data collection period;
- Trends of improvement or regression in foodborne illness risk factor occurrence over time;

- Potential correlations between operational aspects of the industry, such as average number of meals per day, number of employees, complexity of food preparation, and the control of foodborne illness risk factors;
- Potential correlations between elements within regulatory retail food protection programs, such as enrollment in the *FDA Voluntary National Retail Food Regulatory Program Standards*, timing of regulatory inspections, grading systems, posting of inspections results, manager certification requirements and required food handler training, and the control of foodborne illness risk factors, and
- The impact of industry food safety management systems in controlling the occurrence of foodborne illness risk factors.

The results of the study will be used to:

- Provide FDA research information that will assist the agency develop retail food safety initiatives and policies focused on the control of foodborne illness risk factors;
- Identify retail food work plan priorities and allocates resources to enhance retail food safety nationwide;
- Generate nationally representative estimates of the prevalence of foodborne illness risk factors and trends of improvement and regression over time; and
- Recommend best practices and targeted interventions strategies to assist the retail and foodservice industry and state, local, and tribal regulatory professionals with reducing the occurrence of foodborne illness risk factors.

III. Industry Segments and Facility Types Included in the Study

The scope of the Study includes four major segments of the retail and foodservice industries that account for over a million varied and diverse types of operations in the United States:

- Restaurants
- Healthcare Facilities
- Schools (K-12)
- Retail Food Stores

Each of these four major industry segments is comprised of specific facility types that have been defined in Tables 1-4.

Table 1: Description of Facility Types that Comprise the Restaurant Industry Segment

Facility Type	Description
Full Service Restaurants	Establishments where customers place their order at their table; are served their meal at the table, receive the service of the wait staff, and pay at the end of the meal.
Fast Food Restaurants	Also referred to as quick service restaurants and defined as any restaurant that is **not** a full service restaurant. Customers generally order and pay for their meals at a counter.

Table 2: Description of Facility Types that Comprise the Health Care Industry Segment

Facility Type	Description
Hospitals	Foodservice operations that provide for the nutritional needs of inpatients, by preparing meals and transporting them to the patient's room and/or serving meals in a cafeteria setting (meals in the cafeteria may also be served to hospital staff and visitors).
Long-Term Care	Foodservice operations that prepare meals for residents in a group care living setting such as nursing homes and assisted living centers.

Table 3: Description of Facility Types that Comprise the School (K-12) Segment

Facility Type	Description
Base Kitchen	School foodservice facility where meals are fully prepared in the on-site kitchen. Some meals are served to students on-site; other meals are shipped to other locations (including multiple locations within the same school.
On-site Kitchen	School foodservice facility where **all** meals are prepared and serviced on-site.
Combination Kitchen	School foodservice facility in which some meals are prepared and served on-site; but some meals are fully prepared or partially prepared in a central or base kitchen.

Table 4: Description of Facility Types that Comprise the Retail Food Store Segment

Facility Type	Description
Deli Department / Operation	Areas is 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.
Seafood Department / Operation	Areas in a retail food store where seafood is cut, prepared, stored, **or** displayed for sale to the customer.
Produce Department / Operation	Areas in a retail food store where produce is cut, prepared, stored, or displayed for sale to the consumer. A produce operation may include salad bars or juice stations that are operated under the same manager who has responsibility for the produce department.

IV. Data Collection Cycles

In 2013, FDA obtained Office of Management Budget (OMB) approval to initiate the first phase of the Study focused on the data collection within the restaurant segment of the industry. The restaurant data collection was initiated November, 2013 and completed in early October of 2014.

In order to assess trends over time, a minimum of three data points are required for statistical purposes. For the restaurant segment of the industry, two additional data collections are scheduled. The 2nd data collection period for the restaurant industry is scheduled to start October, 2017, and the 3rd data collection period is slated to being October, 2021 as outlined in Table 5

TABLE 5. SUMMARY OF DATA COLLECTION TIME FRAMES

INDUSTRY SEGMENT	FACILITY TYPE	YEAR FOR INITIAL DATA COLLECTION (Baseline Measurement)	2ND DATA COLLECTION PERIOD	3RD DATA COLLECTION PERIOD
Restaurants	Full Service Restaurants Fast Food Restaurants	Nov. 15, 2013 To Sept. 30, 2014	Oct 1, 2017 To Sept 30, 2018	Oct. 1, 2021 To Sept 30, 2022
2nd Data Collection Industry Segments	Health Care Facilities, Retail Food Stores, and Schools (K-12)	Oct. 1, 2015 To Dec. 31, 2016	Oct 1, 2019 To Dec. 31, 2020	Oct. 1, 2023 To Dec. 31, 2024

The second phase of the data collection is planned to be launched in October, 2015. This second data collection period will focus on three industry segments that include healthcare facilities, schools (K-12), and retail food stores. This data collection period will run 15 months and be completed in December, 2016. As with the restaurant segment of the industry, two additional data collection periods are scheduled to provide a basis for assessing trends in the control of foodborne illness risk factors over time. The 2nd data collection period for healthcare facilities, schools, and retail food stores is scheduled to start October, 2019, and the 3rd data collection period is slated to being October, 2023 as outlined in Table 5 above.

V. Selection of Data Collectors

FDA has approximately 25 Regional Retail Food Specialists (Specialists) who serve as the data collectors for the ten-year study. The Specialists are geographically-dispersed throughout the U.S. and possess technical expertise in retail food safety and a solid understanding of the operations within each of the facility types selected for the study. The Specialists are also standardized by FDA's CFSAN personnel in the application and interpretation of the *FDA Food Code*.

VI. Random Selection of Establishments

A geographical information system (GIS) database containing a listing of businesses throughout the U.S. is used as the establishment inventory for the data collection. The geographical distribution of Specialists throughout the U.S. allows for a broad sampling of facility types in all regions of the U.S.; therefore, establishments are randomly selected to participate in the study from among all eligible establishments located within a 150-mile radius of each of the Specialists' home locations. This model provides a reasonably convenient, cost-effective design for generating nationally representative estimates of the prevalence of foodborne illness risk factors and trends of improvement and regression over time.

The random selection of establishments from the GIS database is performed by the FDA's Center for Food Safety and Applied Nutrition (CFSAN) Biostatistics Branch. Prior to distributing the selected establishments to the Specialists, the Biostatistics Branch, working with members of FDA's National Retail Food Team, performs an initial review to ensure establishments are correctly classified and considered eligible to participate in the study based on the facility type descriptions in Tables 1-4.

To further determine the pool of establishments eligible for selection, an assessment is made to exclude operations that handle only pre-packaged food items or conduct low-risk food preparation activities. Annex 5, Table 1 – Risk Categorization of Food Establishments of the *2009 FDA Food Code* contains a grouping of establishments by risk, based on the type of food preparation that is normally conducted within the operation. The vast majority of selected establishments are to be chosen from risk categories 2 through 4.

VII. Sample Size

In order to obtain a sufficient number of observations to conduct statistically significant analysis, the FDA CFSAN Biostatistics Branch has determined, based on the previous ten-year foodborne illness risk factor study, that approximately 400 data collection inspections of each industry segment facility types listed below are needed during initial and subsequent data collection periods:

- Full Service Restaurants (400 data collections/period)
- Fast Food Restaurants (400 data collections/period)
- Healthcare (400 data collections/period)
- Schools (400 data collections/period)
- Retail Food Stores (400 data collections/period)

This sample size provides sufficient observations to be 95% confident that compliance percentages derived from the data collections are within 5% of their actual occurrence.

The sample for each data collection period is evenly distributed among the Specialists.

Given the participation in the study by the industry is voluntary and the status of any given randomly selected establishment is subject to change, substitute establishments will be provided to each Specialist for cases where the facility is misclassified, closed, or otherwise unable or unwilling to participate. The inventory of substitute establishments will be randomly selected by the FDACFSAN Biostatistics Branch and used to replace an ineligible establishment that was included on their original list.

VIII. Preparing for the 2015-2016 Data Collection in Selected Healthcare; School; and Retail Food Store Establishments

With only a few minor exceptions, the data collection protocol and methodology planned for healthcare facilities; schools (K-12); and retail food stores will mirror the restaurant study protocol. The few exceptions are related to unique characteristics related to the different facility types. The data collection elements related to food safety procedures and practices is the same for all the facility types.

Data Collection Procedures and Training

Each Specialist will attend a training webinar prior to initiating the data collection. The training will be provided by members of the FDA National Retail Food Team that have been responsible for the design and assessment of all the Retail Food Risk Factor Study elements. The training will cover all the study components with particular emphasis on the data collection protocol and marking instructions for the data collection form[1]. The workshop training will include written instructions for completing the data collection form that will be used to record the observations made during the visits to the establishments that have been selected for the study.

[1] The data collection forms used by the FDA are available at www.fda.gov/RetailFoodProtection.

Verification of Eligibility of Randomly Selected Restaurants
Each Specialist will receive from FDA's CFSAN Biostatistics Branch, a set of restaurant facilities within their primary area of responsibility that have been randomly selected for the study. Prior to conducting the data collection, the Specialist will contact the state or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist verifies that the restaurant facility has been properly classified (in the correct facility type category) for the purposes of the study and is still in operation. The Specialist ascertains whether the selected restaurant is under legal notice from the state or local regulatory authority. If the selected restaurant is under legal notice, the Specialist will not conduct a data collection in that establishment. The Specialist will remove the establishment from their sample inventory and select another establishment from their list of substitute establishments provided by the FDA CFSAN Biostatistics Branch.

Working with State and Local Regulatory Authorities
As part of the initial contact with the state or local regulatory authority, the Specialist obtains information from the jurisdiction pertaining to the items listed under the heading, "Information on the Regulatory Authority," found on pages 2 and 3 of the Data Collection Form. The data collection fields in this section are the same for all three industry segments (healthcare; schools; retail food stores). At that time, the Specialist will collect the information for the following data collection fields:

- Name of Jurisdiction with Regulatory Oversight;
- Enrolled in FDA Retail Food Program Standards;
- Jurisdiction Meets Standard 1;
- Dates of the Two Most Recent Regulatory Routine Inspections;
- Jurisdiction Uses a Grading System;
- Type of Grading System;
- Jurisdiction's Program Includes Public Reporting of Inspection Results;
- Jurisdiction Has a Mandatory Food Protection Manager Certification Requirement;
- Scope of Food Protection Manager Certification Requirement; and
- Jurisdiction Requires Food Handler Cards

Guidance for completing these data collection information fields is included on pages 17 – 24 in the *FDA Retail Food Program, Foodborne illness Risk Factor Study - Marking Instructions for the Data Collection Form*[2].

The Specialist will extend an invitation to the state or local regulatory authority to accompany him or her on the data collection visit. Should the regulatory authority accept and accompany the Specialist, the Specialist should strongly recommend that the state or local regulatory authority refrain from conducting a regulatory compliance inspection during the data collection visit.

Calibration of Temperature Measuring Devices
Specialists must ensure that thermometers used for each data collection are accurate. The

[2] A copy of this document is available at www.fda.gov/RetailFoodProtection.

Specialists must calibrate their thermometers prior to each establishment data collection visit.

IX. Conducting the Data Collection

Unannounced Data Collection Visits
Each data collection visit is to be unannounced. The intent is to observe the operation in its normal mode, without special preparation to accommodate the data collection visit.

Discuss Purpose of the Data Collection
Upon arrival to the establishment, the Specialist will explain to the owner the purpose of the visit. An introductory letter that explains the purpose of the data collection visit and the study must be used in addition to a verbal explanation. A sample letter is provided in Attachment A. If entry into the selected establishment is denied by the owner or person in charge, the Specialist will not conduct a data collection. The Specialist will select a new establishment from the substitute establishment list provided by the FDA CFSAN Biostatistics Branch.

Conduct a Quick Walk-Through
The primary purpose of the data collection is to observe food safety practices and employee behaviors that are associated with the control of foodborne illness risk factors. After discussing the purpose of the data collection and developing a rapport with the person in charge, the Specialist is to conduct a quick (two to three minute) walk-though of the establishment's kitchen. The goal of the quick walk-though is to identify the critical food preparation processes being conducted at the time of the inspection so that inspection priorities and flow can be determined. For each critical activity observed during the walk-through, the Specialist should determine whether the activity is static (one that will likely be the same over the course in the inspection) or dynamic (one that will likely be completed soon or will change quickly over the course of the inspection).

In addition, the Specialist will need to consider the data that will be needed over the course of the inspection to adequately assess the activities being performed. For instance, if cooling or reheated for hot holding are observed during the quick walk-through, the Specialist will likely need multiple temperature measurements over time to ascertain whether the procedures being used are effective.

During the quick walk-through, the Specialist should ask the operator whether cooking, preparation, cooling, reheating, or receiving are currently being conducted. Specialists should set priorities for the inspection based on the quick walk-through and responses to the operator's questions about the specific activities being conducted at the time of the inspection.

A review of the establishment's menu can provide important information on the type of processes conducted in the operation, but it should be integrated as part of the data collection and not done as a separate interview activity with the person in charge. The Specialist is to use the menu as an information resource as the data collection is being conducted.

Focus on the Primary Data Items

The data collection is intended to be targeted on the control of foodborne illness risk factors. It is not intended to be a comprehensive assessment of compliance with *Food Code* requirements. The focus of the data collection is to be on observations of the primary data items listed on the data collection form.

Data items 1 through 10 are considered primary data items. Each of the primary data items has been placed under the appropriate FDA foodborne illness risk factor category which will be used as the key indicators for FDA's statistical analysis for the study:

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

For each data collection, the Specialists should make every effort to observe procedures and practices related to the primary data items. Comprehensive guidance for marking observations of primary data items is provided on pages 62 – 82 of the FDA Retail Food Program, Foodborne Illness Risk Factor Study – Marking Instruction for the Data Collection Form.

Other Areas of Interest – Data Items

Data items 11 through 19 are listed under the heading "Other Areas of Interest." These food safety practices and procedures directly support active managerial control of the foodborne illness risk factor areas addressed under the primary data items:

- **Other Areas of Interest**
    11. Handwashing facilities are accessible and properly maintained
    12. Employees practice good hygiene
    13. Consumers are properly advised of risks of consuming raw or undercooked animal foods
    14. Time alone is properly used as a public health control
    15. Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces

16. Special processes are conducted in compliance with issued variance / HACCP Plan, when required
17. Food is received from safe sources
18. Toxic materials are identified, used and stored properly
19. Management and food employees are trained in food allergy awareness as it relates to their assigned duties

Specialists should be cognizant of opportunities to observe these data items during the data collection. The same type of risk assessment and dynamic-static evaluation used for the primary data items can also be applied to those listed under the "Other Areas of Interest" in establishing priorities for the data collection. For example, assessing whether an establishment has an accurate thermometer for checking internal food temperatures or whether there is a chemical test kit for checking sanitization concentration, which are part of data item 15, can be done at anytime during the data collection because these items are static in nature. In contrast, the opportunity to assess a reduced oxygen packaging process during the data inspection is dynamic because quantitative measurements must be made at critical production points. A reduced oxygen packaging process also has an inherently high food safety risk if done improperly.

Comprehensive guidance for marking observations of data items listed under the "Other Areas of Interest" is provided on pages 83 – 96 of the FDA Retail Food Program, Foodborne Illness Risk Factor Study – Marking Instruction for the Data Collection Form.

Information Statements

Under most of the data items, a list of information statements is provided. These information statements are preceded by a letter for organization purposes and describe a specific observation (food safety practice) associated with the overarching data item under which it is listed. For example, the information statements for the Data Item #1 –

Employees practice proper handwashing are:

A. Hands are cleaned and properly washed using hand cleanser / water supply / appropriate drying methods / length of time as specified in Section 2-301.12 of the *Food Code*.
B. Hands are cleaned and properly washed when required as specified in 2-301.14 of the *Food Code.*

The information statements provide a method for:

- Conducting comparisons with the previous ten-year risk factor study (1998-2008). Some of the information statements were included as data items on the data collection form used for the first study;
- Recording observations made. Data collectors have an option to check a box rather than write a narrative statement; and
- Enhancing quality assurance pertaining to the interpretation of the data collected. Standard statements provide a means for maintaining uniformity and consistency among multiple data collectors.

Documenting Observations of Food Safety Practices
Using the current version of the *FDA Food Code,* the data collector will determine whether the observations made of the employee food safety practices or behaviors contained in the information statements were **IN** Compliance, **OUT** of Compliance, Not Observed (**NO**), or Not Applicable (**NA**). The recorded markings of the information statements are then used to determine the compliance status of the corresponding data item.

An observation is based on an evaluation of one or more occurrences of a data item or information statement at an establishment. Specific instructions for marking each data item and information statement are provided in the FDA Retail Food Program, Foodborne Illness Risk Factor Study – Marking Instruction for the Data Collection Form. The four marking options are defined as follows:

- **IN –** means that all observed occurrences were **IN** Compliance with the appropriate *FDA Food Code* provision for the data item or information statement.
- **OUT** – means that one or more of the observations made were **OUT** of Compliance with the appropriate *FDA Food Code* provision for the data item or information statement. An explanation of the specific criteria used for determining **OUT** of Compliance for each data item is to be recorded by the data collector on the data collection form.
- **NO** – means the data item or information statement was **Not Observed** during the inspection. The **NO** marking is used when an information statement is a usual practice in the food establishment, but the practice is **NOT** observed during the time of the inspection.
- **NA –** means the data item or information statement is Not Applicable. The NA marking is used when a data item or information statement is **NOT** a function of the food establishment.

Quantitative measurements are to be made with calibrated thermocouples, heat sensitive tape or maximum registering thermometers, and chemical test strips. Quantitative temperature measurements are to be recorded in the food temperature charts provided on the data collection form. Sanitization measurements should be recorded in the comment section for the specific data item observed.

Recording Food Product Temperatures
The Specialist will record ALL food product temperatures measured during the data collection in the charts provided under data items that contain specific product temperature critical limits. A partial illustration for the temperature chart for data item #5 – is provided below:

Table 5: Cold Holding Temperatures Recorded During the Data Collection (List all Temperatures Taken)

FOOD PRODUCT	FOOD TEMP	*FOOD CODE* CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT	FOOD PRODUCT	FOOD TEMP.	*FOOD CODE* CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT
Cooked Chicken	**40ºF**	**41ºF**	**Walk-in Cooler**	**Diced Ham**	**44ºF**	**41ºF**	**Refrigerated Sandwich Preperation Table**
Raw Hamburger Patty	**52ºF**	**41ºF**	**Refrigeration Drawer Preparation Line**	**Cooked Pasta**	**39ºF**	**41ºF**	**Walk-in Cooler**
Sliced Tomatoes	**48ºF**	**41ºF**	**Refrigerated Sandwich Preparation Table**	**Cooked Ribs**	**41ºF**	**41ºF**	**Walk-in Cooler**
Egg Salad	**42ºF**	**41ºF**	**Refrigerated Sandwich Preparation Table**	**Tuna Salad**	**42ºF**	**41ºF**	**Refrigerated Sandwich Preparation Table**

The database that will be used to record the data has been designed to provide a drop down menu for the *Food Code Critical Limits* for each temperature-based data item. Using the food product temperature entered by the Specialist, the database has been programmed to automatically calculate the difference between the food product temperature recorded by the Specialist and the *Food Code* critical limit. The database system will then use this information to automatically enter the correct totals in the summary of product temperatures table depicted below. The Specialist will not have to manually complete the product temperature summary tables.

NUMBER OF FOOD PRODUCT TEMPERATURES	SUMMARY COLD HOLDING PRODUCT TEMPERATURE CATEGORIES
3	I. Number of product temperature measurements **IN** Compliance with *Food Code* critical limits
2	II. Number of **OUT** of Compliance product temperature measurements **1ºF - 2ºF** above *Food Code* critical limits
1	III. Number of **OUT** of Compliance product temperature measurements **3ºF - 4ºF** above *Food Code* critical limits
1	IV. Number of **OUT** of Compliance product temperature measurements **5ºF - 9ºF** above *Food Code* critical limits
1	V. Number of **OUT** of Compliance product temperature measurements **10ºF or more** above *Food Code* critical limits

Handwashing Frequency Assessment

The Specialist will record all of his or her handwashing observations during the regular data collection using the "Handwashing Frequency Assessment" located under data item #1 – Employees practice proper handwashing on the Data Collection Form. Over the course of the data collection visit, the Specialist will record a tally of each time an employee is observed doing the following:

- Washing hands properly and when required,
- Washing hands improperly, or
- Failing to wash hand when required.

Specialists should recognize their limitations with this aspect of the Study. The assessment of handwashing frequency in the context of this study is intended to provide a broad-based indicator of handwashing practices and will not be used to draw statistical correlations. It will be impossible to assess every activity during which handwashing should occur so the precision needed for statistical analysis will not be achievable. Specialists should not forgo an opportunity to observe a food safety practice or procedure related to a primary data item in order to observe food employees who may need to wash their hands at some point in an ongoing food preparation activity.

Handwashing frequency data will be collected throughout the normal course of the data collection for other food safety procedures and practices. Additional inspection time should not be allocated for collection of this data.

Assessment of Food Safety Management Systems

In addition to collecting information on compliance with the *FDA Food Code*, Specialists will obtain information on the extent to which food establishments have developed and implemented food safety management systems. FDA will use this information to examine the correlations, if any, between the degree to which management systems are in place and the control of foodborne illness risk factors.

The Food Safety Management System Assessment will be conducted during the same establishment visit but independent from the determination of *Food Code* compliance for individual data items. The Food Safety Management System Assessment is to be conducted at an appropriate time so it does not compromise a Specialist's opportunity to observe food safety practices or procedures related to the primary data items.

The 2013 data collection will focus on the food safety management system in place to control four key foodborne illness risk factors and selected items for each as presented below:

- **Poor Personal Hygiene**
    1. Employees practice proper handwashing
    2. Employees do not contact ready-to-eat foods with bare hands

- **Contaminated Equipment / Protection from Contamination**
    3. Food is protected from cross-contamination during preparation, and display
    4. Food contact surfaces are properly cleaned and sanitized

- **Improper Holding / Time-Temperature Control**
    5. Foods requiring refrigeration are held at the proper temperature
    6. Foods displayed or stored hot are held at the proper temperature
    7. Foods are cooled properly
    8. Refrigerated, ready-to-eats foods are properly date marked and discarded within 7 days of preparation or opening

- **Inadequate Cooking**
    9. Raw animal foods are cooked to required temperatures
    10. Cooked foods are reheated to required temperatures

Each randomly selected establishment will have a management system assessment conducted for **ONE** of the four foodborne illness risk factor areas described above. The FDA CFSAN Biostatistics Branch will randomly select the risk factor area for which a food safety management system assessment is to be conducted for each establishment.

The data collector will evaluate the presence of three key food safety management system elements (procedures, training, and monitoring) for all the **primary data items** listed under the assigned risk factor.

- ***Procedures*** – A defined set of actions adopted by food service management for accomplishing a task in a way that minimizes food safety risks.
- ***Training*** – Management informs employees what the procedures are and teaches the employees how to carry them out. This is **not** to be used for determining manager knowledge or certification
- ***Monitoring*** – Routine observations and measurements made by management to determine if procedures are being followed and maintained.

For each of these three food safety management system elements, the data collector will determine if the information provided by the establishment management adequately addresses the essential critical limits for the assigned risk factor area. A food safety management system assessment questionnaire has been developed for each of the foodborne illness risk factor areas. The questionnaire for each of the risk factor areas requires the Specialist to enter a YES or NO response for the following four statements:

- Management is able to describe the critical limits for *(the specific risk factor procedure or practice)* as they apply to their establishment.
- 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 *(the specific risk factor procedure or practice).*
- Management is able to produce written materials (SOPs; posters; wall charts; wallet cards; etc.) that support the implementation of their *(the specific risk factor procedure or practice)* within their establishment

Using the food safety management system assessment tool, the data collector will add up the total number of "YES" responses for each of the management system elements (Procedures, Training, and Monitoring). The number of "YES" responses on the assessment tool will determine how to mark the Procedures, Training, And Monitoring sections for the data item on the data collection form. Comprehensive guidance for marking the food safety management system assessment (Procedures; Training; and Monitoring) for selected risk factor areas is provided on pages 55 – 58 of the FDA Retail Food Program, Foodborne Illness Risk Factor Study – Marking Instruction for the Data Collection Form.

Establishment Information
During the course of the data collection, the Specialist will obtain information from the owner/person in charge related to items listed in the following Sections on pages 1, 4, and 5 of the Data Collection Form:

- Establishment Information
- Establishments that are Part of Multi-Unit Operations
- Manager Certification
- Employee Health Policy
- Highly Susceptible Populations (Only Healthcare facilities)

Guidance for completing the information fields associated with these sections of the data collection form is provided on pages 1 – 16 and 25 – 40 of the *FDA Retail Food Program, Foodborne Illness Risk Factor Study – Marking Instructions for the Data Collection Form.*

This information can be obtained at any time during the data collection and should not take precedence over, or inhibit, the Specialist's observations of actual food safety practices and procedures related to the primary data items. Specialists should consider the static nature of this information and prioritize the collection of this information accordingly.

Corrective Actions – Observations that Pose a Significant Public Health Risk
Though industry participation in the Study is voluntary, correction action is to be obtained for observations that pose a significant public health risk. If conditions observed during the data collection visit pose a significant public health risk, the Specialist is to discuss the situation with the person in charge and seek to obtain voluntary corrective action. FDA's experience from data collections performed as part of its previous study indicate that in all but a few instances, industry responded in a cooperative and responsible manner to alleviate potential public health risks.

Should an instance occur where an observation during the data collection poses a significant public health risk and corrective action cannot be voluntarily obtained, the Specialist should contact the appropriate regulatory authority to ensure appropriate corrective actions are taken. This is an example of a situation where it is advantageous to have the responsible regulatory authority accompany the Specialist during the data collection.

Exit Briefing with Person in charge

The data collection visit is conducted as part of a research project and is not intended to be a regulatory compliance inspection. No written report is left with the establishment. Upon completion of the data collection, the Specialist conducts an exit briefing with the owner or person in charge to discuss significant findings and answer any questions.

X. Entering the Data – Transition from ACCESS Database to Web-Based Platform

During the 2013-2014 restaurant data collection, each Specialist was provided with a copy of an ACCESS database software program that had been specifically formatted to store and analyze data collected during the study. The Specialists manually entered their observations for each of the data items and information statements for the selected establishment into the ACCESS database.

Over the past three years, FDA has been working with the National Center for Food Protection and Defense (NCFPD) to develop and maintain a web-based database platform for the retail food risk factor study. The web-based database platform will be located as part of the FoodSHIELD site. The FoodSHIELD database has been designed not only for use by FDA but for state/local/tribal jurisdictions seeking a system to store and maintain data from their own studies. Firewalls have been built into the design of the database system to maintain the security and integrity of data entered by each jurisdiction.

The database system also contains the option of "permission-based" sharing of data between jurisdictions. This feature has the potential of creating more robust data sets for analyzing trends in the occurrence of foodborne illness risk factors over time within the retail food segment of the industry.

For the 2015-2016 Healthcare, School, and Retail food store data collection, FDA will use the web-based database platform located in FoodSHIELD to store and maintain the data from the Study. During this period of time, FDA is planning on uploading the data from its recently completed restaurant data collection from the ACCESS database to the FoodSHIELD system.

XI. **Piloting the Use of Hand Held Technology**

The FoodSHIELD retail food risk factor study database has been designed to accommodate both manual entry of data and uploading electronic reports from hand held technology. During the 2015-2016 data collection, FDA will begin the transition process from manual data entry to the use of hand held technology. As part of an agency-wide initiative to assess the use of hand held technology, FDA will have 5 Specialists conduct their data collections using hand held tablets. The information from the hand held tablets will be transferred "real-time" into the FoodSHIELD database via a web browser. Based on the lessons-learned from the hand-held technology pilot, FDA will assess the type of equipment and support system needed to fully integrate hand held technology for future data collections. Specialist who are not provided hand held technology will continue to manually enter data directly into the FoodSHIELD system.

Webinar trainings and pilot data entries will be conducted so Specialists have a solid understanding of the data entry features built into the FoodSHIELD system. Specialist designated for the use of hand-held technology will conduct field pilot testing of the equipment and upload data to the FoodSHIELD database prior to the start of the 2015-2016 data collection.

XII. **Reports from Previous FDA Retail Food Risk Factors Studies**

The following reports from FDA's previous risk factors studies are available from the following web links:

Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000)
http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm123546.pdf

Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004)
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction//ucm423850.pdf

Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009)
http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224682.pdf

Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998 – 2008)
http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224152.pdf

Attachment A – Example Introductory Letter for Establishments Selected for the Study

[DATE]

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:

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/default.htm

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0744 (Expiration Date: 08/30/2024). The time required to complete this information collection is estimated to average 73 minutes per response for the person in charge of a fast food restaurant, 106 minutes for the person in charge of a full service restaurant, 180 minutes for the person in charge of a retail food store, and 30 minutes for the program director (or designated individual) of the regulatory authority. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRASTAFF@fda.hhs.gov.

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 [Specialist's phone number].

Sincerely

[Specialist's contact information]