U.S. Food and Drug Administration

Study on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2023)

(Restaurant Segment)

Protocol for the Data Collection

Revised February 28, 2013

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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. 2013-2023 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 three 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
- Institutional Foodservice
- Retail Food Stores

For this study, nine facility types have been chosen from these three different foodservice and retail food industry segments. Tables 1-3 provide a description of each facility type comprising each industry segment included in the study.

TABLE 1: DESCRIPTION OF FACILITY TYPES THAT COMPRISE THE RESTAURANT INDUSTRY SEGMENT

Industry Segment	Facility Type	Description
Restaurants	**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 INSTITUTIONAL FOODSERVICE INDUSTRY SEGMENT

Industry Segment	Facility Type	Description
Institutional Foodservice	**Hospitals**	Foodservice operations that serve patients, staff, and hospital visitors in a traditional hospital setting. Individuals who are acutely ill to those who are immune-compromised are a target population for the data collection.
	Nursing Homes	Foodservice operations that serve highly susceptible populations living in a group care setting. The elderly (55+ years) is the target populations for the data collection. Also includes assisted living facilities.
	Elementary Schools (K-5)	Foodservice operations that serve students from one or more grade levels from preschool through Grade 5. Young children are a target population for the data collection.

TABLE 3: DESCRIPTION OF FACILITY TYPES THAT COMPRISE THE RETAIL FOOD STORE INDUSTRY SEGMENT

Industry Segment	Facility Type	Description
Retail Food Stores	**Deli Departments/Stores**	Departments in retail food stores or stand-alone stores where potentially hazardous foods (time/temperature control for safety foods) such as luncheon meats and cheeses are sliced for the customer and where sandwiches and salads are prepared on-site or received from a commissary in bulk containers, portioned, and displayed. Freestanding cheese shops are categorized as delis. Parts of the deli may include: ● Salad bars and other food bars maintained by the deli department manager; ● Areas where meat or poultry are cooked and offered for sale as ready-to-eat; and ● Limited bakery operations attached to or adjacent to the deli and maintained by the deli department manager.
	Meat & Poultry Departments/Markets	Meat and poultry departments in a retail food store, as well as any freestanding meat market or butcher shop that sells raw meat or poultry directly to the consumer.
	Seafood Departments/Markets	Seafood departments in a retail food store and freestanding seafood markets that sell seafood directly to the consumer including the preparation of raw and/or ready-to-eat seafood. In-store sushi bars are considered part of the seafood department for the purposes of the data collection.
	Produce Departments/Markets	Areas or departments where produce is cut, prepared, stored, or displayed. A produce department may include salad bars or juicer stations that are managed by the produce managers

IV. Data Collection Cycles

In 2013, FDA will conduct a pilot data collection to practice the use of the data collection form and methods and test exportation of the pilot data into a central repository. Following the pilot, FDA plans to conduct annual data collections beginning in October, 2013 with the initial data collection for select restaurant facility types, followed by the initial data collection for select institutional facility types in October, 2014 and select

retail food facility types in October, 2015. The results of the initial data collection for each of the facility types will serve as the baseline measurement from which trends will be analyzed. Two additional data collection periods for each of the facility types are planned at three-year intervals after the initial data collection for purposes of analyzing trends. The scheduled data collection cycles are described in Table 4.

TABLE 4. SUMMARY OF DATA COLLECTION TIME FRAMES

INDUSTRY SEGMENT	FACILITY TYPE	FDA FY YEAR FOR INITIAL DATA COLLECTION (Baseline Measurement)	2ND DATA COLLECTION PERIOD	3RD DATA COLLECTION PERIOD
Restaurants	Full Service Restaurants	2014	2017	2020
	Fast Food Restaurants			
Institutional Foodservice	Hospitals	2015	2018	2021
	Nursing Homes			
	Elementary Schools (K-5)			
Retail Food Store	Deli Departments/Stores	2016	2019	2022
	Meat & Poultry Depts./Markets			
	Seafood Depts./Markets			
	Produce Depts./Markets			

NOTE: Data collections for each of the facility types within an industry segment will be conducted using a three-year interval period.

V. Selection of Data Collectors

FDA has approximately 25 Regional Retail Food Specialists (Specialists) who will 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. will be 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 will be 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 will be 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, will perform 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 1-3.

To further determine the pool of establishments eligible for selection, an effort will be 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 facility type are needed during initial and subsequent data collection periods. 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 will be 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 selected for each Specialist for cases where the facility is misclassified, closed, or otherwise unable or unwilling to participate. The inventory of substitute establishments will remain with the FDA CFSAN Biostatistics Branch until needed by a Specialist to replace an ineligible establishment that was included on their original list.

VIII. Preparing for the 2013 Data Collection in Select Restaurant Facility Types

Data Collection Procedures and Training

Each Specialist will attend a training workshop 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. A draft of the FDA – Retail Food Program, Foodborne Illness Risk Factor Study Data Collection Form (Data Collection Form) that will be used for the 2013 Study period focused on the restaurant segment of the industry is included as Attachment A. 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 restaurants that have been selected for the study.

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 will verify 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 should also ascertain 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 restaurant from their sample inventory and contact the FDA CFSAN Biostatistics Branch for a substitute restaurant facility. The Specialist should also obtain a substitute facility from the FDA CFSAN Biostatistics Branch for any situation where the originally selected restaurant is closed or otherwise inaccessible to conduct a data collection.

Working with State and Local Regulatory Authorities

As part of the initial contact with the state or local regulatory authority, the Specialist will obtain 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 (Attachment A). 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;
- Inspections Report By;
- Jurisdiction Has a Mandatory Food Protection Manager Certification Requirement;
- Scope of Food Protection Manager Certification Requirement;
- Food Protection Manager Certification Program Elements;
- Jurisdiction Requires Food Handler Cards; and

- Type of Training/Test for Food Handler Card.

Guidance for completing these data collection information fields is included on pages 5 – 13 in the *FDA Retail Food Program, Foodborne illness Risk Factor Study - Marking Instructions for the Data Collection Form*.

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, 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 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 should be used in addition to a verbal explanation. A sample letter is provided in Attachment B. 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 contact the FDA CFSAN Biostatistics Branch and request a substitute restaurant establishment as a replacement.

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 an 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 temperatures
  - #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 43 – 64 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**
  - Data Item #11 – Handwashing facilities are accessible and properly maintained
  - Data Item #12 – Employees practice good hygiene
  - Data Item #13 – Consumers are properly advised of risks of consuming raw or undercooked animal foods
  - Data Item #14 – Time alone is properly used as a public health control
  - Data Item #15 – Facilities have adequate equipment and tools for ensuring food temperature control and sanitization of food contact surfaces
  - Data Item #16 – Special processes are conducted in compliance with issued variance / HACCP Plan, when required
  - Data Item #17 – Food is received from safe sources
  - Data Item #18 – Toxic materials are identified, used and stored properly
  - Data Item #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 65 – 78 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:

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**

The ACCESS 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 ACCESS 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 ACCESS 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 (Attachment A). 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**
  Data Item #1 – Employees practice proper handwashing
  Data Item #2 – Employees do not contact ready-to-eat foods with bare hands

- **Contaminated Equipment / Protection Food 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 Control**
  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-eats 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

Each randomly selected restaurant 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 restaurant establishment.

Examples of the types of questions that the Specialist may ask to assess an establishment's food safety management system for cooking raw animal foods are presented below. This list is not intended to be all-inclusive, nor is the expectation that a Specialist ask all the questions provided or ask them in any specific order. The intent is to provide a framework for obtaining the necessary information on what type of procedures are in place for cooking; what training is provided to food employees to ensure they follow the established cooking procedures, and what type of system is in place to monitor final cook temperatures. This same type of framework can be customized and applied to each of the risk factor areas.

- Are specific procedures (directions) in place for cooking foods?
  - ✓ Are the cooking procedures product specific (roasts; hamburgers, etc)?

  - ✓ Are any cooking procedures based on equipment temperature for a set amount of time?
  - ✓ Is a slow cook process used for any of the food products (roasts)?
  - ✓ Do you receive steaks that are from whole muscle-intact beef?
- How do your food employees know the correct cooking temperatures?
- How are cooking temperatures monitored to ensure the food is ready for service to the customer?
- What type of equipment is used to measure the final internal product cooking temperature?
- What actions do employees take when food does not reach proper temperature?
- Do you maintain any type of cooking logs or records?
- Are there any meats that are partially cooked or seared then cooled in preparation for large volumes?
- Are raw animal foods cooked to customer order (rare, medium-rare, medium, well-done)? If so, what food items?
- If foods are cooked to customer order does the establishment have a consumer advisory?

The Specialist evaluates the presence and adequacy of all three management system elements (procedures, training, and monitoring) for all the data items listed under the selected risk factor. For each data item that falls under the assigned risk factor, a separate assessment will be made of the three food safety management system components using a rating scale of 1 to 4. The rating number reflects the relative degree to which each component of the management system is developed and implemented by the food establishment.

Each rating number is broadly defined below:

1 – Non-Existent:	No system in place or 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 & Documented	System is complete, consistent and written. The preponderance of the management system is written. This is the goal for all establishments.

Establishment Information
During the course of the data collection, the Specialist obtains 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 (Attachment A):

- Establishment Information
- Establishments that are Part of Multi-Unit Operations
- Manager Certification
- Employee Health Policy

Guidance for completing the information fields associated with these sections of the data collection form is provided on pages 1 – 4 and 14 – 23 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 into an ACCESS Database

Entering Data
Each Specialist will be provided with a copy of the ACCESS database software program that has been specifically formatted to store and analyze data collected during the study. The Specialists will enter their observations for each of the data items and information statements for the selected establishment into the ACCESS database.

Quality Assurance Check
Before saving a record, the Specialist will conduct a quality assurance check that has been integrated as part of the ACCESS database, to ensure that all required data entry fields have been completed and are accurate. A menu icon has been integrated into the database. Clicking on the icon will trigger a database search of data collection fields that may have been inadvertently left blank or data collection field where the Specialist has entered information that is inconsistent with the marking instructions for the study. The Specialists will be prompted to correct the data collection error. This quality assurance function will continue automatically until all data entry errors have been rectified.

XI. Exporting Records to a Central Database

When the Specialist has completed collecting data for all their randomly selected facilities, the ACCESS database that has been installed on their computer should be prepared for 'Exporting' to a central database. Directions for 'Exporting the Database' will be provided to the Specialists. At the beginning of each data collection period, a specific FDA National Retail Food Team member will be assigned the responsibility for maintaining the central database for the study. The central database will include all of the Specialists' records from the establishments that have been randomly selected for that specific data collection period.

XII. Importing Records to a Central Database

The FDA National Retail Food Team member responsible for maintaining the study's central database will conduct a quality assurance review of the records received to ensure accuracy prior to importing into the system. Upon completion of the QA review, the Specialist's records will be 'Imported' into the central database. A QA review will be conducted after the 'Importing' function is completed to ensure that no duplicate records or overriding of existing records has occurred.

XIII. 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/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm089696.htm

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

STUDY PROTOCOL ATTACHMENTS

FDA RETAIL FOOD PROGRAM
FOODBORNE ILLNESS RISK FACTOR STUDY
DATA COLLECTION FORM

ESTABLISHMENT INFORMATION			
Date:		**Data Collector:**	
Time In:	**Time Out:**	**Total Time in Minutes:**	
Establishment Name:			
Street Address:			
City:	**State:**	**Zip:**	**County:**
Industry Segment:	**Facility Type:**	**Risk Categorization:**	
Seating Capacity:		**Average Number of Meals Per Day:**	
Maximum Number of Employees Per Shift:		**Number of Employees Present at Time of Visit:**	
Activity level at the time of visit (*Select* ***ONE*****):** ☐ **Light** ☐ **Moderate** ☐ **Heavy**			

ESTABLISHMENTS THAT ARE PART OF MULTI-UNIT OPERATIONS
Establishment is part of a Multi-Unit Operation: ☐ **YES** ☐ **NO**
Number of Individual Units that are part of the Multi-Unit Operation *(Enter the number of units provided by the person in charge)***:**
Ownership of Establishment *(Select* ***ONE*** *of the following)***:** ☐ **Company-Owned** ☐ **Franchise** ☐ **Unsure**
If Franchise – number of units owned by the franchisee *(Enter the number of units provided by the person in charge)***:**

FDA RETAIL FOOD PROGRAM
FOODBORNE ILLNESS RISK FACTOR STUDY
DATA COLLECTION FORM

INFORMATION ON THE REGULATORY AUTHORITY
Name of Jurisdiction with Regulatory Oversight:
Enrolled in FDA Retail Food Program Standards: ☐ **YES** ☐ **NO**
Jurisdiction Meets Standard 1 *(Select **ONE** of the following)*: ☐ **YES – Self Reported** ☐ **YES – Verified by Audit** ☐ **NO – Jurisdiction does not meet Standard 1**
Dates of the Two Most Recent Regulatory Routine Inspections: Date 1: Date 2:
Jurisdiction Uses a Grading System *(Select **ONE** of the following)*: ☐ **YES – Numerical Score** ☐ **YES – Letter Grade** ☐ **YES – Color Graphic** ☐ **YES – Numerical Score and Letter Grade** ☐ **YES – Numerical Score and Color Graphic** ☐ **YES – Letter Grade and Color Graphic** ☐ **YES – Numerical Score, Letter Grade, and Color Graphic** ☐ **YES – Other** ☐ **NO – Jurisdiction does not have a grading system** **If "Other" *describe*:**
Jurisdiction's Program Includes Public Reporting of Inspection Results *(Select **ONE** of the following)*: ☐ **YES – Posting on-site** ☐ **YES – Posting on the Internet** ☐ **YES – Posting on-site and Posting on the Internet** ☐ **YES – Other** ☐ **NO – Jurisdiction does not require inspections to be publically reported** **If "Other" *describe*:**
Jurisdiction Has a Mandatory Food Protection Manager Certification Requirement *(Select **ONE** of the following)*: ☐ **YES – Based ONLY on successful completion of an ANSI-Accredited Program** ☐ **YES – Other Food Protection Manager Certification Program (not an ANSI-Accredited Program)** ☐ **YES – Other AND Reciprocal Acceptance of an ANSI Accredited Program** ☐ **NO – Jurisdiction does not have a mandatory Food Protection Manager Certification Requirement**
If "Other" *(Select **ONE** of the following)* ☐ **Other includes a required Training Component** ☐ **Other includes a Test other than exams offered through an ANSI Accredited Programs** ☐ **Other includes a required Training Component AND Test other than exam offered through an ANSI Accredited Program** **If "Other" *describe*:**

INFORMATION ON THE REGULATORY AUTHORITY (continued from previous page)
Scope of Food Protection Manager Certification Requirement *(Select **ONE** of the following)***:** ☐ **Person in Charge – One Per Establishment** ☐ **Person in Charge – Present at All Times** ☐ **Supervisory Employee – One Per Establishment** ☐ **Supervisory Employee – Present at All Times** ☐ **Other** **If "Other"** ***describe*****:**
Jurisdiction Requires Food Handler Card *(Select **ONE** of the following)***:** ☐ **YES – Required Training** ☐ **YES – Required Test** ☐ **YES – Required Training and Test** ☐ **YES – Other** ☐ **NO – Jurisdiction does NOT require Food Handler Cards** **If "Other"** ***describe*****:**

FDA RETAIL FOOD PROGRAM
FOODBORNE ILLNESS RISK FACTOR STUDY
DATA COLLECTION FORM

MANAGER CERTIFICATION
1. Is there a certified food protection manager <u>EMPLOYED</u> at the establishment (*Select <u>ONE</u>*)? ☐ **YES – Certificate Available** ☐ **YES – Certificate <u>NOT</u> Available** ☐ **NO – No certified food protection managers are employed at the establishment** **If the marking above contains a "YES" response, indicate the Type of Certification below (*Select <u>ONE</u>*)** ☐ **ANSI-Accredited** ☐ **Other** ☐ **Unsure**
2. Is there an employee who is a certified food protection manager <u>PRESENT</u> during the data collection (*Select <u>ONE</u>*)? ☐ **YES – Certificate Available** ☐ **YES – Certificate <u>NOT</u> Available** ☐ **NO – No certified food protection managers are present during the data collection** **If the marking above contains a "YES" response, indicate the Type of Certification below (*Select <u>ONE</u>*)** ☐ **ANSI-Accredited** ☐ **Other** ☐ **Unsure**
3. Is the <u>PERSON IN CHARGE</u> at the time of the data collection a certified food protection manager (*Select <u>ONE</u>*)? ☐ **YES – Certificate Available** ☐ **YES – Certificate <u>NOT</u> Available** ☐ **NO – The person in charge at the time of the data collection is NOT a certified food protection manager** **If the marking above contains a "YES" response, indicate the Type of Certification below (*Select <u>ONE</u>*)** ☐ **ANSI-Accredited** ☐ **Other** ☐ **Unsure**
4. Is the establishment's policy to have a certified food protection manager present at all times? ☐ **YES** ☐ **NO**
If "Other" for one or more of the responses to questions 1 – 3, *describe*:

FDA RETAIL FOOD PROGRAM
FOODBORNE ILLNESS RISK FACTOR STUDY
DATA COLLECTION FORM

EMPLOYEE HEALTH POLICY
1. Food employees exhibiting certain illness symptoms or conditions that require exclusion or restriction in the *Food Code*, ARE OBSERVED within the establishment during the data collection. ☐ **YES – Employees exhibiting illness symptoms or conditions observed within the establishment** ☐ **NO – Employees exhibiting illness symptoms or conditions NOT observed within the establishment**
2. Are food employees and conditional employees informed of their responsibility to report to the person in charge illness SYMPTOMS as specified in Section 2-201.11 of the *Food Code*? ☐ **YES – Policy is ORAL** ☐ **YES – Policy is WRITTEN** ☐ **NO – No Policy in place**
3. Are food employees and conditional employees informed of their responsibility to report to the person in charge diagnosis with, or exposure to, the specific ILLNESSES specified in Section 2-201.11 of the *Food Code*? ☐ **YES – Policy is ORAL** ☐ **YES – Policy is WRITTEN** ☐ **NO – No Policy in place**
4. Is management aware of its responsibility to NOTIFY THE REGULATORY AUTHORITY when a food employee is jaundiced or diagnosed with an illness due to a pathogen specified in Section 2-201.11 of the *Food Code*? ☐ **YES – Policy is ORAL** ☐ **YES – Policy is WRITTEN** ☐ **NO – No Policy in place**
5. Is the management's employee health policy consistent with 2-201.12 of the *Food Code* for EXCLUDING AND RESTRICTING food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods? ☐ **YES – Policy is ORAL** ☐ **YES – Policy is WRITTEN** ☐ **NO – No Policy in place**
6. Is the management's employee health policy consistent with 2-201.13 of the *Food Code* for REMOVAL OF EXCLUSIONS AND RESTRICTIONS of food employees and conditional employees on the basis of their health and activities as they relate to diseases that are transmitted through foods? ☐ **YES – Policy is ORAL** ☐ **YES – Policy is WRITTEN** ☐ **NO – No Policy in place**
7. Management has a copy of FDA's *Employee Health and Personal Hygiene Handbook OR cd database*? ☐ **YES** ☐ **NO**

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

IN	OUT	NO	NA	
☐	☐			**1. Employees practice proper handwashing**

IN	OUT	NO	NA	Description of HANDWASHING OBSERVATIONS
☐	☐			***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 Section 2-301.14 of the *Food Code*

COMMENTS:

HANDWASHING FREQUENCY ASSESSMENT

	C1 Employee observed washing hands properly and when required	C2 Employee observed washing hands improperly	C3 Employee observed failing to wash hand when required
TOTAL COUNT			

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES		TRAINING		MONITORING	
☐ 1	**COMMENTS:**	☐ 1	**COMMENTS:**	☐ 1	**COMMENTS:**
☐ 2		☐ 2		☐ 2	
☐ 3		☐ 3		☐ 3	
☐ 4		☐ 4		☐ 4	

IN	OUT	NO	NA	
☐	☐			**2. Food employees do not contact ready-to-eat foods with bare hands**

COMMENTS:

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES		TRAINING		MONITORING	
☐ 1	**COMMENTS:**	☐ 1	**COMMENTS:**	☐ 1	**COMMENTS:**
☐ 2		☐ 2		☐ 2	
☐ 3		☐ 3		☐ 3	
☐ 4		☐ 4		☐ 4	

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

IN	OUT	NO	NA	
☐	☐			**3. Food is protected from cross-contamination during storage, preparation, and display**

IN	OUT	NO	NA	Description of FOOD Contamination OBSERVATIONS
☐	☐	☐	☐	**A.** Raw animal foods are separated from ready-to-eat foods
☐	☐	☐	☐	**B.** Different raw animal foods are separated from each other
☐	☐			**C.** Food is protected from environmental contamination – actual contamination observed
☐	☐			**D.** Food is protected from environmental contamination – potential contamination
☐	☐		☐	**E.** Other (*describe in the comments section below)*

COMMENTS:

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT								
PROCEDURES			**TRAINING**			**MONITORING**		
☐	**1**	**COMMENTS:**	☐	**1**	**COMMENTS:**	☐	**1**	**COMMENTS:**
☐	**2**		☐	**2**		☐	**2**	
☐	**3**		☐	**3**		☐	**3**	
☐	**4**		☐	**4**		☐	**4**	

IN	OUT	NO	NA	
☐	☐			**4. Food contact surfaces are properly cleaned and sanitized**

IN	OUT	NO	NA	Description of Food Contact Surfaces OBSERVATIONS
☐	☐			**A.** Food contact surfaces and utensils are clean to sight and touch and sanitized before use
☐	☐	☐	☐	**B.** Equipment food contact surfaces and utensils are cleaned and sanitized properly using manual warewashing procedures
☐	☐	☐	☐	**C.** Equipment food contact surfaces and utensils are cleaned and sanitized properly using mechanical warewashing equipment
☐	☐		☐	**D.** Other (*describe in the comments section below)*

COMMENTS:

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT								
PROCEDURES			**TRAINING**			**MONITORING**		
☐	**1**	**COMMENTS:**	☐	**1**	**COMMENTS:**	☐	**1**	**COMMENTS:**
☐	**2**		☐	**2**		☐	**2**	
☐	**3**		☐	**3**		☐	**3**	
☐	**4**		☐	**4**		☐	**4**	

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

IN	OUT	NO	NA	
☐	☐			**5. Foods requiring refrigeration are held at the proper temperature**

IN	OUT	NO	NA	Description of Cold Holding Temperature OBSERVATIONS
☐	☐			**A.** TCS Food is maintained at 41˚F (5˚C) or below, except during preparation, cooking, cooling, or when time is used as a public health control
☐	☐	☐	☐	**B.** Raw shell eggs are stored under refrigeration that maintains ambient air temperature of 45ºF (7ºC) or less
☐	☐		☐	**C.** Other (describe in the temperature chart and comments section below)

COMMENTS:

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

FOOD PRODUCT	FOOD TEMP.	*FOOD CODE* CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT	FOOD PRODUCT	FOOD TEMP.	*FOOD CODE* CRITICAL LIMIT	TYPE OF COLD HOLDING EQUIPMENT

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

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	**COMMENTS:**	☐	1	**COMMENTS:**	☐	1	**COMMENTS:**
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	

IN	OUT	NO	NA	
☐	☐	☐	☐	**6. Foods displayed or stored hot are held at the proper temperature**

IN	OUT	NO	NA	Description of Hot Holding Temperature OBSERVATIONS
☐	☐	☐	☐	**A.** TCS Food is maintained at 135˚F (57˚C) or above, except during preparation, cooking, cooling, or when time is used as a public health control.
☐	☐	☐	☐	**B.** Roasts are held at a temperature of 130˚F (54˚C) or above
☐	☐	■	☐	**C.** Other (describe in the temperature chart and comments section below)

COMMENTS:

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

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

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

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	**COMMENTS:**	☐	1	**COMMENTS:**	☐	1	**COMMENTS:**
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	

IN	OUT	NO	NA	
☐	☐	☐	☐	**7. Foods are cooled properly**

IN	OUT	NO	NA	Description of Cooling Temperature OBSERVATIONS
☐	☐	☐	☐	**A.** Cooked TCS Food is cooled from 135˚F (57˚C) to 70˚F (21˚C) within 2 hours **and** from 135˚F (57˚C) to 41˚F (5˚C) or below within 6 hours
☐	☐	☐	☐	**B.** TCS Food (prepared from ingredients at ambient temperature) is cooled to 41˚F (5˚C) or below within 4 hours
☐	☐	☐	☐	**C.** Proper cooling methods / equipment are used
☐	☐	■	☐	**D.** Other (describe in the temperature chart and comments section below)

COMMENTS:

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

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

FOOD SAFTEY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES			TRAINING			MONITORING		
☐	1	**COMMENTS:**	☐	1	**COMMENTS:**	☐	1	**COMMENTS:**
☐	2		☐	2		☐	2	
☐	3		☐	3		☐	3	
☐	4		☐	4		☐	4	

IN	OUT	NO	NA	
☐	☐	☐	☐	**8. Refrigerated, ready-to-eat foods are properly date marked and discarded within 7 days of preparation or opening**

IN	OUT	NO	NA	Description of Date Marking OBSERVATIONS
☐	☐	☐	☐	**A.** Ready-to-eat, TCS Food (prepared on-site) held for more than 24 hours is date marked as required
☐	☐	☐	☐	**B.** Open commercial containers of prepared ready-to-eat TCS Food held for more than 24 hours are date marked as required
☐	☐	☐	☐	**C.** Ready-to-eat, TCS Food prepared on-site and/or opened commercial container exceeding 7 days at ≤ 41°F is discarded
☐	☐	■	☐	**D.** Other (describe in the temperature chart and comments section below)

COMMENTS:

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT								
PROCEDURES			**TRAINING**			**MONITORING**		
☐	**1**	**COMMENTS:**	☐	**1**	**COMMENTS:**	☐	**1**	**COMMENTS:**
☐	**2**		☐	**2**		☐	**2**	
☐	**3**		☐	**3**		☐	**3**	
☐	**4**		☐	**4**		☐	**4**	

Risk Factor – Inadequate Cooking (Items 9&10)

IN	OUT	NO	NA	
☐	☐	☐	☐	**9. Raw animal foods are cooked to required temperatures**

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

COMMENTS:

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

FOOD PRODUCT	FINAL COOK TEMP.	*FOOD CODE* CRITICAL LIMIT	CONSUMER ADVISORY		FOOD PRODUCT	FINAL COOK TEMP.	*FOOD CODE* CRITICAL LIMIT	CONSUMER ADVISORY	
			YES	NO				YES	NO
			☐	☐				☐	☐
			☐	☐				☐	☐
			☐	☐				☐	☐
			☐	☐				☐	☐
			☐	☐				☐	☐

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

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES		TRAINING		MONITORING	
☐ 1	**COMMENTS:**	☐ 1	**COMMENTS:**	☐ 1	**COMMENTS:**
☐ 2		☐ 2		☐ 2	
☐ 3		☐ 3		☐ 3	
☐ 4		☐ 4		☐ 4	

IN	OUT	NO	NA	
☐	☐	☐	☐	**10. Cooked foods are reheated to required temperatures**

IN	OUT	NO	NA	Description of Reheating Temperature OBSERVATIONS
☐	☐	☐	☐	**A.** TCS Food that is cooked and cooled on premises is rapidly reheated to 165˚F (74˚C) for 15 seconds for hot holding
☐	☐	☐	☐	**B.** Commercially-processed ready-to-eat food, reheated to 135˚F (57˚C) or above **for hot holding**
☐	☐	■	☐	**C.** Other Reheating Observations (describe in the Comments Section and Temperature Chart below)

COMMENTS:

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

FOOD PRODUCT	FINAL REHEAT TEMP.	*FOOD CODE* CRITICAL LIMIT	FOOD PRODUCT	FINAL REHEAT TEMP.	*FOOD CODE* CRITICAL LIMIT

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

FOOD SAFETY MANAGEMENT SYSTEM ASSESSMENT

PROCEDURES		TRAINING		MONITORING	
☐ 1	**COMMENTS:**	☐ 1	**COMMENTS:**	☐ 1	**COMMENTS:**
☐ 2		☐ 2		☐ 2	
☐ 3		☐ 3		☐ 3	
☐ 4		☐ 4		☐ 4	

Other Areas of Interest (Items 11-19)

- **NOTE: This section will be used to develop data items that are not part of the primary research area for Retail Food Risk Factor Study but may provide important information that will assist other food safety initiatives within the agency**

IN	OUT	NO	NA	
☐	☐			**11. Handwashing facilities are accessible and properly maintained**
IN	**OUT**	**NO**	**NA**	**Description of OBSERVATIONS of Handwashing Facilities**
☐	☐			**A.** Handwashing facilities are conveniently located and accessible for employees
☐	☐			**B.** Handwashing facilities are supplied with hand cleanser / disposable towels / hand drying devices
COMMENTS:				

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

IN	OUT	NO	NA	
☐	☐		☐	**13. Consumers are properly advised of risks of consuming raw or undercooked animal foods**
COMMENTS:				

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

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

IN	OUT	NO	NA	
☐	☐	☐	☐	**16. Special processes are conducted in compliance with issued variance / HACCP Plan, when required**

IN	OUT	NO	NA	Description of OBSERVATIONS of Specialized Processes
☐	☐	☐	☐	***A.*** Food establishment conducts reduced oxygen packaging without a variance as specified in Section 3-502.12 of the *Food Code*
☐	☐	☐	☐	***B.*** Food establishment performs specialized process in accordance with approved variance and HACCP Plan when required
☐	☐	☐	☐	***C.*** Juice packaged in the food establishment is treated under a HACCP Plan to reduce pathogens or labeled as specified in Section 3-404.11 of the *Food Code*
☐	☐	■	☐	***D.*** Other (describe in the comments section below)

COMMENTS:

IN	OUT	NO	NA	
☐	☐	■	■	**17. Food is received from safe sources**

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

COMMENTS:

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

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

Attachment B – 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. 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. 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 ensure the anonymity of participating establishments. 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

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]