FDA Report on the
Occurrence of Foodborne Illness Risk Factors
in Selected Institutional Foodservice,
Restaurant, and Retail Food Store Facility Types
(2009)

Prepared by the FDA National Retail Food Team

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EXECUTIVE SUMMARY

In 2008, the U.S. Food and Drug Administration's (FDA) National Retail Food Team conducted the third phase of a three-phase,10-year study to measure the occurrence of practices and behaviors commonly identified by the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks. Specifically, the study called for conducting data collection inspections of various types of foodservice and retail food establishments at five-year intervals to observe and document practices and behaviors that relate to the following CDC contributing factor categories associated with foodborne illness outbreaks within foodservice and retail food establishments, herein referred to as foodborne illness risk factors (risk factors):

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

This 2009 report is the third report in a series and presents findings based on data collected in 2008. The first report in the study was issued in August 2000 and presented the findings from the first data collection effort in 1998. A second report was issued in 2004 and presented data collected in 2003. FDA intends to publish a report in 2010 that compares the results from the three data collection periods and examines what trends, if any, were observed.

The 2000 and 2004 reports called attention to the need for greater active managerial control of foodborne illness risk factors. They suggested that more innovative and effective strategies to improve food safety practices in retail and foodservice establishments were needed. The reports highlighted operational areas most in need of improvement including employee handwashing, cold holding of potentially hazardous foods (time/temperature control for safety foods), date marking of ready-to-eat foods, and cleaning and sanitizing of food contact surfaces.

In each phase of the study, FDA Regional Retail Food Specialists collected data during site visits of over 800 establishments representing nine distinct facility types. Direct observations, supplemented with information gained from discussions with management and food employees, were used to document the establishments' compliance status for 42 individual data items based on provisions in the 1997 FDA Food Code. In each establishment, the compliance status for each data item was recorded in terms of IN Compliance, Out of Compliance, Not Observed (meaning the behavior or practice was applicable but not observed during the visit), or Not Applicable (meaning the behavior or practice did not apply to the establishment).

For each of the nine facility types, the percentage of observations recorded as Out of Compliance is presented for each risk factor and for the individual data items related to

those risk factors most in need of priority attention. The percent Out of Compliance value for each risk factor was calculated by dividing the total number of Out of Compliance observations of data items in the risk factor by the total number of observations (IN compliance and Out of Compliance) of data items in the risk factor. The percent Out of Compliance values for individual data items were calculated by dividing the total number of Out of Compliance observations for the individual data item by the total number of observations (IN and Out of Compliance) for the data item.

The data presented in this 2009 report indicate that some of the same risk factors and data items identified as problem areas in the 2000 and 2004 Reports remain in need of priority attention. This indicates that industry and regulatory efforts to promote active managerial control of these risk factors must be enhanced. The Out of Compliance percentages remained high for data items related to the following risk factors:

- Improper Holding/Time and Temperature
- Poor Personal Hygiene
- Contaminated Equipment/Protection from Contamination

For the improper holding/time and temperature risk factor, the high percent Out of Compliance values were most commonly associated with improper cold holding of potentially hazardous food (PHF)/time-temperature control for safety (TCS) food and inadequate date marking of refrigerated, ready-to-eat PHF/TCS Food.

Within the poor personal hygiene risk factor, the proper, adequate handwashing data item had the highest percent Out of Compliance value for every facility type. Percent Out of Compliance values for proper, adequate handwashing ranged from approximately 18% for meat departments to approximately 76% for full service restaurants.

Of the data items related to the contaminated equipment/protection from contamination risk factor, improper cleaning and sanitizing of food-contact surfaces before use was the item most commonly observed to be Out of Compliance in eight out of the nine facility types. Percent Out of Compliance values for this data item ranged from 18% in seafood departments to 64% in full service restaurants.

As in the 2004 Report, this 2009 report includes a comparison between the data collected from food establishments that had a Certified Food Protection Manager (CFPM) from a program recognized by the Conference for Food Protection and those that did not. The results of the study indicate that the presence of a Certified Food Protection Manager is positively correlated to the overall IN Compliance percentages in certain facility types, especially in delis, full service restaurants, seafood departments, and produce departments. Poor Personal Hygiene, Improper Holding/Time and Temperature, and Contaminated Equipment/Protection from Contamination appear to be the risk factors for which the presence of a certified manager had the most positive correlation.

The 2003 and 2008 data collection efforts included several supplemental data items that were not included in the 1998 data collection. While original 42 data items in the study remained the same from 1998 to 2008, the supplemental data items addressed changes made to the *FDA Food Code* since 1997. These items related to the cooking temperature for pork, the minimum hot holding temperatures, employee health, juice, eggs, and highly susceptible populations. Data gathered for the supplemental data items suggest that reducing the minimum hot holding temperature for PHF/TCS foods from 140°F (60°C) to 135°F (57°C) and reducing the minimum cooking temperature for pork from 155°F (68°C) to 145°F (63°C) had minimal effect on the industry's control of these risk factors.

Results from the 2008 data collection indicate that the recommendations made to foodservice and retail food operators and regulators in the 2000 and 2004 Reports need to be reemphasized. Foodservice and retail food store operators must ensure that their management systems are designed to achieve active managerial control over the risk factors. Likewise, regulators must ensure that their inspection, education, and enforcement efforts are geared toward the control of the risk factors commonly found to be Out of Compliance.

I. INTRODUCTION AND PURPOSE

A. Background

Ensuring safe food is an important public health priority for our nation. For years, regulatory and industry food safety programs have focused on reducing the incidence of foodborne illness. Despite these efforts, the 1996 report, "Reinventing Food Regulations" [National Performance Review], concluded that foodborne illness caused by harmful bacteria and other pathogenic microorganisms in meat, poultry, seafood, dairy products, and a host of other foods is a significant public health problem in the United States.

The National Performance Review Report looked at the occurrence of foodborne illness from a farm-to-table perspective. It did not attempt to define the scope of the problem within specific sectors of the farm-to-table continuum. In order to determine the effectiveness of regulatory and industry food safety programs within foodservice and retail food store facility types, a study was needed that would assess information associated with the occurrence of foodborne illness and be specific to this segment of the industry.

FDA's Response to the 1996 National Performance Review Report

In response to the 1996 National Performance Review Report and subsequent input from state and local regulatory partners, FDA established the National Retail Food Steering Committee (Steering Committee) including representation from the Center for Food Safety and Applied Nutrition (CFSAN), Office of Regulatory Affairs (ORA), Division of Federal/State Relations (DFSR), Division of Human Resource Development (DHRD), and the Interstate Travel Program (ITP) Field Team. The Steering Committee is responsible for reviewing retail food program objectives and coordinating program activities.

The 1993 Government Performance and Results Act required federal agencies to develop performance plans that included measurable goals and performance indicators. To establish a strategic direction for the retail food program, the Steering Committee made it a priority to identify a performance measurement to assess the effectiveness of the nation's retail food protection system. The initiatives in the subsequent strategic plan were directed toward developing a national retail food program model that could be used by federal, state, local, and tribal regulatory 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 performance indicator that justifies program resources and allocates them to program areas that will provide the most significant public health benefits.

Identifying Performance Measures for Regulatory Retail Food Programs

Although the level of foodborne illness would be the ideal retail food program performance indicator, the occurrence of foodborne illness is grossly underreported. This makes the incidence of foodborne illness an unreliable program measurement. As an alternative, the occurrence of foodborne illness risk factors was selected as the performance indicator. The *Centers for Disease Control and Prevention (CDC)* Surveillance Report for 1988 – 1992 identifies the most significant contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within foodservice and retail food store facility types:

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

For the purposes of this long-term study, FDA designated these five contributing factors as "risk factors." Using the results from the 1998 data collection as a baseline, the Steering Committee has established a goal of reducing the Out of Compliance percentage of observations of the original 42 data items related to foodborne illness risk factors in institutional foodservice, restaurants, and retail food store establishments by 25% by 2010.

Study Timeline

Any study designed to measure trends requires analysis of the subject matter over a period of time. No single point in time can be used to derive conclusions. Rather, it is a review and evaluation of the data collected at several intervals that provide the basis for drawing conclusions.

This project was designed to collect data on the occurrence of the foodborne illness risk factors in selected foodservice and retail food establishments at five-year intervals. These data collection efforts are designed to get an accurate picture of the extent to which foodservice and retail food store operations have control over the risk factors during each data collection period.

In order to detect trends of improvement and/or regression of effort to control foodborne illness risk factors, it is necessary to collect data from at least three, and preferably more, periods in time. Using the data from the 1998, 2003, and 2008 data collection periods, FDA will evaluate trends and determine whether progress is being made toward the goals of reducing the occurrence of foodborne illness risk factors. FDA

plans to release a trend analysis report covering the 1998-2008 span of this study in early 2010.

Table 1
Study Timeline

Data Collection Period	Title of the Report	Project Objectives
1998	Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors. Published in 2000	Establish a Baseline for nine selected institutional foodservice, restaurant, & retail food store facility types
2003	FDA Report on the Occurrence of Foodborne Illness Risk Factors within Selected Institutional Foodservice; Restaurant & Retail Food Store Facility Types (2004)	Identify risk factors and data items in need of priority attention. Collect second of at least three sets of data needed to assess trends in occurrence of risk factors.
2008	FDA Report on the Occurrence of Foodborne Illness Risk Factors within Selected Institutional Foodservice; Restaurant & Retail Food Store Facility Types (2009)	Identify risk factors and data items in need of priority attention. Collect third of at least three sets of data needed to assess trends in occurrence of risk factors.

1998 Study Established the First National Baseline

Using the results of the 1998 data collection, the 2000 Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors established the first-ever national baseline on the occurrence of foodborne illness risk factors within institutional foodservice, restaurant, and retail food store facility types. By establishing a baseline, regulatory and industry food safety professionals have a performance measure upon which to assess the impact of efforts directed to positively change behaviors and practices related to foodborne illness.

The data in Table 2 presents the IN Compliance status of 42 data items used to establish the 1998 Baseline measurements and the FDA 2010 improvement goal for each of the nine facility types included in the study. These measurements represent the "overall IN Compliance percentages" for each of the nine facility types.

Table 2

Percentage (%) of Observations found IN Compliance for ALL Data Items

Industry Segment	Facility Type	1998 Baseline % IN Compliance for Observations made of ALL data items (rounded to nearest %)*	2010 FDA Improvement Goal (rounded to nearest %)
	Hospital	80%	85%
Institutions	Nursing Home	82%	87%
	Elementary School	80%	85%
Restaurants	Fast Food	74%	81%
restaurants	Full Service	60%	70%
	Deli	73%	80%
Retail Food	Meat & Poultry	81%	86%
	Seafood	83%	87%
	Produce	76%	82%

*1998 Baseline calculation:

Percent IN Compliance =

All applicable, observable, IN Compliance data items within all risk factor categories x 100%

Total number of observations (IN and OUT)

*To be consistent with the Retail Food Steering Committee's established performance goal, a ten-year goal of 25% reduction for the percent Out of Compliance was set as the target for improvement. An example computation using hospitals illustrates how the specific ten-year improvement goal percentages were attained:

Hospital: 1998 Baseline % = 80% IN Compliance (20% Out of Compliance)

Improvement goal = 25% reduction in the percent Out of Compliance

25% of 20% = 5%

Baseline Out of Compliance 20% - 5% = 15%Improvement goal = 85% IN Compliance

NOTE: The definitions for IN Compliance; Out of Compliance; Not Observed; and Not Applicable observations are presented on pages 32-33 of this report.

2008 Study should be interpreted as a separate stand-alone report

The FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurants and Retail Food Facility Types (2009) summarizes results from the third data collection conducted in 2008. The results contained in this report provide insight into the effectiveness of industry management systems and food safety regulatory programs in controlling foodborne illness risk factors in certain retail food store and foodservice operations. This report should be read and the data interpreted as a separate stand-alone report. This report makes no attempt to draw comparisons between the results of the 1998, 2003, and 2008 data collections.

Separate Report will examine trends for the research period 1998 - 2008

With the third data collection (2008) completed, FDA plans to release a separate report in early 2010 that examines the improvement or regression in the percentage of IN Compliance observations for each facility type. Statistical analysis will be used to assess trends at the facility type level and the risk factor level. The report will also examine the effect of selected data items on the improvement or regression in the IN Compliance observations for risk factors and facility types. Having data from three separate years over a ten-year span (1998, 2003, and 2008) should shed some light on the nature of changes in the occurrence of risk factors in foodservice and retail food store establishments that are taking place.

B. Study Design and Objectives

This study contains nine separate reports of data analyses, one for each of the nine different facility types. The target industry segments for this project are institutional foodservice, restaurants, and retail food stores. Of the nine facility types, three were associated with institutional foodservice – hospitals, nursing homes, and elementary schools (K-5). The restaurant industry segment was comprised of two facility types – fast food and full service. Four facility types were departments of retail food stores and independent specialty operations related to deli, meat and poultry, seafood, and produce.

Although the data presented were collected from many locations across the U.S., this study was not designed to support comparisons of states, counties, cities, or even regions of the U.S. The data from this project provided input into the Healthy People 2010 Initiative under Food Safety Objective 10.6. This objective is designed to improve food preparation practices and food employee behaviors within institutional food service establishments, restaurants, and retail food stores.

C. <u>Introduction</u>

Guidance for interpreting the results in this Report

All statistical studies have limitations. How a research project is designed and implemented can have a profound impact on the interpretation of the data. Prior to discussing methodology and data results, it is essential to review what the 2008 study was designed to do and, equally important, what it was NOT designed to do.

Without this discussion, the data presented may quite easily be misinterpreted or used inappropriately.

This study was designed using assessment criteria based on the 1997 FDA Food Code

The project is designed to track the foodservice and retail food industries' control of foodborne illness risk factors using specific requirements in the 1997 FDA Food Code. Since one of the purposes of the project is to track changes in the percent of IN Compliance observations related to industry's efforts to control foodborne illness risk factors, the standard of measurement used to evaluate these comparisons must remain constant for each of the data collection periods (1998, 2003, and 2008). For example, suppose the recommended standard in the Food Code was relaxed and we changed the data item accordingly. If the compliance percentage is then found to increase, we would not know whether this was due to better employee practices or simply the change in the recommended standard.

The data collection inspection form used for this report (pages 18 to 26) contains two sections. Forty-two individual data items comprise the first section of the form. Each of the data items is listed under one of the foodborne illness risk factors. These 42 data items have remained the same for all three data collection periods (1998, 2003, and 2008).

Since 1997, the *FDA Food Code* has been updated several times. A second section has been included on the data collection inspection form under the title, "Supplemental Items," to assess the impact of changes made in the *1997 FDA Food Code* on IN Compliance percentages for foodborne illness risk factors and data items. The design of the data collection inspection form ensures a means to track changes over time against a constant standard of measure and provides a mechanism for evaluating the potential impact of changes in *Food Code* provisions on the data collected.

Only a couple of individual data items within the study contain criteria or critical limits that have been updated since the release of the 1997 FDA Food Code. A comparative assessment was conducted on what impact, if any, these changes in the Food Code had on the overall IN compliance percentages. The results and discussion of these data items are presented in Section VI. Additional Areas of Study.

The study was not designed to measure regulatory compliance with specific state or local food codes

The 42 data items used to track changes in the occurrence of foodborne illness risk factors were based on provisions in the 1997 FDA Food Code. No attempt was made to determine if an establishment would have been found to be IN Compliance with prevailing state, local, or tribal regulations.

The FDA Food Code is neither federal law nor federal regulation and is not preemptive of state, local, or tribal food safety requirements. In many cases, the FDA Food Code and prevailing regulatory standards of measurement were the same.

For some data items, the standard of measurement was different. Foodservice industry practices observed by the Specialists may have been IN Compliance with less stringent state or local laws even though the report notes they were not IN Compliance with the 1997 FDA Food Code. Differences in state and/or local requirements have no bearing on the findings in this study since the 1997 FDA Food Code was the assessment criterion. By using the 1997 FDA Food Code as the standard of measurement, the study employed a single document of foodservice and retail food store safety standards that have undergone national review.

This study was designed to assess industry management systems essential to the control of foodborne illness risk factors

In the 1998, 2003, and 2008 FDA data collections, observations were made for multiple data items (*FDA Food Code* requirements) that comprise food safety practices and employee behaviors specific to each of the five risk factors.

Some of these individual data items did not have a direct link to human illness, but were essential to the active managerial control of foodborne illness risk factors. Examples include:

- Availability of hand soap and sanitary towels/hand drying devices in the Poor Person Hygiene risk factor, which included an assessment of proper handwashing. Improper handwashing is directly associated with the spread of pathogens and the occurrence of foodborne illness. The availability of hand soap and sanitary towels/hand drying devices, though not directly linked to human illness, is an essential component of the management system needed to ensure proper handwashing.
- Retention of shellstock tags in the Food from Unsafe Sources risk factor.
- Date marking of ready-to-eat PHF/TCS foods in the Improper Holding/Time and Temperature risk factor, which included quantifiable measurements of food product holding times and temperatures.

An additional category, "Other," was included to capture potential food safety risks related to possible contamination by toxic or unapproved chemicals for each of the facility types.

This study was designed to focus only on a specific point in the farm-to-table food safety continuum

Pathogens may enter the food supply at any point in the farm-to-table food safety continuum. All industry sectors within this continuum have a responsibility for ensuring safe food.

The 1998, 2003, and 2008 data collections cover only facility types that comprise institutional foodservice, restaurant, and retail food store operations. The report does not attempt to assess the occurrence of foodborne illness risk factors within other sectors of the food industry or in private homes.

Consumers may find the information in this report useful when trying to better understand food safety risks. This report, however, does not provide specific information about the relative risks associated with the many options consumers have when it comes to dining and purchasing food.

Specific retail food safety information is available to consumers from a number of sources including public web sites maintained by federal, state, and local regulatory agencies, universities, consumer organizations, as well as the foodservice and retail food industries. One such federal food safety site is www.foodsafety.gov.

Study Design Summary

This study is intended to fill a void that currently exists in the assessment of program effectiveness for controlling foodborne illness risk factors. It identifies the most urgent priorities for improvement. The following table provides a summary of the purpose and objectives of the ten-year study.

Table 3
Study Design Objectives

	The Study IS NOT Designed to
Measure trends over time in regulatory and industry efforts to reduce the occurrence of foodborne illness risk factors	Support comparisons of geographic areas, states, counties, cities or chains of foodservice/retail food store operations
Assess the occurrence of foodborne illness risk factors and management practices essential to their control in selected institutional foodservice, restaurant and retail food store facility types	Assess the occurrence of foodborne illness risk factors in other industry sectors of the farm-to-table continuum
Use the 1997 FDA Food Code provisions as the standard of measurement upon which to make observations of employee practices and behaviors	Determine an establishment's regulatory compliance with prevailing state, local, or tribal regulations
Identify employee practices and behaviors that contribute to the occurrence of foodborne illness that are in need of priority attention	Correlate the occurrence of foodborne illness risk factors with actual incidences of human illness

II. METHODOLOGY

In order to detect trends of improvement and/or regression from the 1998 baseline measurements, it is critical that the methodology used to collect data, as well as the study design, remain consistent for each data collection. For the 2003 and 2008 data collection periods, supplemental data items were added to capture additional information not collected in 1998. The following sections of the report present an overview of the methodology used in this study as originally designed in 1998. In addition, unique elements that were included as part of the 2003 and 2008 data collections (i.e. supplemental data items) are described.

A. Selection of Facility Types

For this study, nine facility types were chosen from three different segments of the foodservice and retail food industries.

INSTITUTIONAL FOODSERVICE

- Hospitals
- Nursing Homes
- Elementary Schools

RESTAURANTS

- Fast Food Restaurants
- Full Service Restaurants

RETAIL FOOD STORES

- Deli Departments
- Meat and Poultry Departments
- Seafood Departments
- Produce Departments

The selected institutional foodservice, restaurant, and retail food store facility types included in this project represent over a million varied and diverse types of operations in the United States.

A direct focus on these industry segments allows FDA to track trends in the occurrence of foodborne illness risk factors in the vast majority of establishment types at the retail level that serve both general and highly susceptible populations. For the purposes of this report, a highly susceptible population is a group of persons in a segregated environment who are more likely than the general population to experience foodborne disease due to their current health status or age, such as those found in hospitals, nursing homes, and elementary schools.

B. Eligibility of Establishments for Selection

In determining the pool of establishments eligible for selection, an effort was made to exclude operations that handle only pre-packaged food items or conduct low-risk food preparation activities.

Establishments that were selected included moderate to high-risk operations such as establishments that:

- Served a highly susceptible population (i.e., hospitals, nursing homes, elementary schools);
- Handled ingredients extensively; or
- Conducted a variety of food preparation processes.

Annex 4 of the 1997 FDA Food Code contains a suggested protocol for grouping establishments by risk. The following Risk Categorization of Food Establishments summary provided a general guideline for determining the type of establishments included in the study.

Table 4

Risk Categorization of Food Establishments

RISK TYPE	RISK TYPE CATEGORY DESCRIPTION
1	Pre-packaged, non-potentially hazardous foods only. Limited preparation of non-potentially hazardous foods only.
2	Limited menu (one or two main items). Pre-packaged, raw ingredients are cooked or prepared to order. Retail food operations exclude deli or seafood operations departments. Raw ingredients require minimal assembly. Most products are cooked/prepared and served immediately. Hot and cold holding of potentially hazardous foods is restricted to single meal service. Preparation processes requiring cooking, cooling, and reheating are limited to one or two potentially hazardous foods.
3	Extensive handling of raw ingredients. Preparation process includes the cooking, cooling, and reheating of potentially hazardous foods. A variety of processes require hot and cold holding of potentially hazardous food. Advance preparation for next day-service is limited to two or three items. Retail food operations include deli and seafood departments. Establishments doing food processing at retail.
4	Extensive handling of raw ingredients. Preparation processes include the cooking, cooling, and reheating of potentially hazardous foods. A variety of processes require hot and cold holding of potentially hazardous foods. Food processes include advanced preparation for next-day service. Category would also include those facilities whose primary service population is immunocompromised.
5	Extensive handling of raw ingredients. Food processing at the retail level, e.g., smoking and curing, reduced oxygen packaging for extended shelf-life.

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The vast majority of selected establishments fell into risk categories 3 - 5 based on their operational practices and populations served. Due to limited food preparation or handling, some meat and poultry, seafood, and produce departments in retail food stores may have been risk category 2. These facility types were included in this study because foodborne illness outbreaks have been associated with certain products sold in these departments.

C. Selection of Data Collectors

FDA Regional Retail Food Specialists (Specialists) located throughout the nation were chosen as the data collectors for this study. Each Specialist possessed technical expertise in retail food safety and a solid understanding of the operations inherent to each of the nine facility types chosen. In addition, Specialists were standardized in the consistent and uniform application of the control measures in the *FDA Food Code* and possessed a strong working knowledge of the foodborne illness risk factors. Selection of the Specialists as data collectors strengthened consistency and uniformity in assessing employee behaviors and practices within their work environment. In addition, the Specialists comprised a group within which implementation of the project could be easily coordinated and standardized.

D. Selection of Geographical Locations

The geographical distribution of Specialists throughout the country allowed for a broad sampling of establishments throughout all regions of the U.S. The choice of data collection locations, therefore, was based on the Specialists' geographical areas of responsibility and provided a reasonably convenient design for estimating national risk-related behaviors and practices.

An improved design for measuring trends within the foodservice and retail food industries would be one based on probability sampling of the whole nation in which the number of establishments inspected within any given location would be related to the volume of retail food consumed within that location. This would have required the development of comprehensive establishment lists for randomly selected locations around the country, and excessive travel would have been cost-prohibitive and eliminated other vital work by FDA.

E. Random Selection of Establishments Using Comparison Set Lists

For the 1998 data collection period, each Specialist developed five Comparison Set Lists for each of the facility types. In most cases, each comparison set list was comprised of between 10 and 20 establishments located in a geographical area. For a few facility types, particularly nursing homes and hospitals, the number of establishments within a designated geographical area was limited. For these facility types, a comparison set list may have included as few as four establishments. Establishments were placed on each list in alphabetical order. Table 5 that appears on the following page provides an illustration of a hypothetical Comparison Set List.

Table 5
Comparison Set List

FDA Region	Central
FDA Specialist	Jane Doe
Industry Segment	Restaurant
Facility Type	Fast Food
Establishment Risk Category	3
Comparison Set List Number	List 1 of 5

Note: If a facility is randomly chosen, but not inspected, note the reason in the Notes section at the bottom of the page.

			(Yes	or No)
Facility Name	Facility Address	Phone #	Random #	Inspected?
			Chosen?	
1. Anytime Food	1 Ocean Dr., Ocean Park, IL	123-4561	Yes	Yes
2. Big Pizzas	23 Pizza Place, Pepperoni, IL	123-4562		
3. Crazy Time Food	101 Broadway, Ocean Park, IL	123-4563	Yes	Yes
4. Delicious Eats	240 Baltic Avenue, Monopoly, IL	123-4564		
5. Dig These Dogs	6437 Oak St., Pepperoni, IL	123-4565		
6. Hungry Horses	972 E. West St., Ocean Park, IL	123-4566	Yes	Yes
7. Make Your Own Sandwich	1 Elm St., Monopoly, IL	123-4567		
8. Tasty Treats	567 Illinois Ave, Monopoly, IL	123-4568		
9. Try R Food	1919 Park Place, Monopoly, IL	123-4569		
10. Zesty Delights	8134 W. East St,, Ocean Park, IL	123-4570	Yes	No

NOTES:

1998 – Establishment #6 randomly selected and inspected.

2003 (1st Attempt) – Establishment #10 randomly selected but was closed for business.

2003 (2nd Attempt) – Establishment #3 randomly selected and inspected.

2008 – Establishment #1 randomly selected and inspected.

In order to maintain consistency between data collection periods, the Specialists used the 1998 Comparison Set Lists in 2003 and for the most part used them again in 2008. By the start of the 2008 data collection, a few of the comparison set lists developed in 1998 became unusable because there were no establishments remaining on the list. This occurred because during the 10-year period of the Study, some of the establishments on the original 1998 lists had closed, relocated, or changed their type of operation so they no longer fit the facility type for the comparison set list on which they were originally placed.

For example, an establishment may have been originally placed on a comparison set list for fast food restaurants, but at the time of the 2008 data collection, the restaurant had changed to a full service restaurant. Since it no longer met the fast food facility type category, it could not be selected for data collection within this facility type. Selection bias was reduced by using a random number table to choose the establishments that were to be inspected. For example, using the hypothetical

Comparison Set List on page 15, the Hungry Horses establishment was selected and inspected in 1998. In 2003, Zesty Delights was selected at random but was not inspected because it was out of business. Thus, the Specialist randomly selected another establishment from the same list – Crazy Time Food. In 2008, Anytime Food was selected and inspected.

Only one establishment was inspected from each comparison set list during each data collection period. In addition, an establishment could not be reselected from the same comparison set list if other eligible establishments that had not previously been selected remained on the list. For instance, if in 2008 a Specialist randomly selected an establishment that had already been inspected in 1998, the Specialist would have drawn another random number until an establishment on the comparison set list was chosen that had not been previously inspected.

If in 2008, however, all the eligible establishments on a comparison set list had been randomly selected for data collection at some previous point during the course of the Study, the Specialist could have completed a data collection in a randomly selected establishment that was part of the 1998 or 2003 Study. This scenario was extremely rare and was associated with a few lists that contained an unusual number of establishments that closed, relocated, or changed business operations during the 10-year research period.

F. Number of Inspections Conducted

In 2008, a total of 850 inspections were conducted by FDA Regional Retail Food Specialists. Based on the number of inspections planned, each Specialist attempted to inspect at least five establishments from each of the nine facility types for a total of 45 inspections.

G. Data Collection Form

So that data could be collected for *specific* behaviors and practices associated with each foodborne illness risk factor, the data collection form used for this study was divided into subparts. For example, rather than capturing all the behaviors and practices related to the Inadequate Cooking risk factor under one data item and being unable to discern which particular behavior or practice was in need of attention, there were 12 different types of observations that could be made, each corresponding to its own data item.

The data collection form used in 1998 included 42 individual data items sorted among the five foodborne illness risk factors and a sixth category called "Other," for the potential risks related to toxic or unapproved chemicals. Each of the 42 data items was based on the 1997 FDA Food Code for all three data collection periods.

The *Food Code* continued to be updated periodically during the ten-year span of the study. Some of the changes in the *FDA Food Code* relate to the original 42 data items; others are new provisions used to address emerging food safety concerns. To capture data for these changes, an additional section, "Supplemental Data Items," was added to the data collection form in 2003. The same 2003 "Supplemental Data Items" were

included in the 2008 data collection. The requirements in the 2001 FDA Food Code were used as the basis for the supplemental data items.

The Data Collection Form included in this report on pages 18-26 was used for each establishment that was inspected.

2008 DATA COLLECTION FORM (page 1 of 9)

FDA

Foodborne Illness Risk Factor Study Data Collection Form

Date:				
Time In: Time Out:				Inspector:
Data Colle		ng:		
Establish				Manager:
Physical A	Address:			
City: State:	Zip:	County:		Industry Segment: Facility Type:
Certified	Food Pro	tection Manager:	YES	NO
41	°F (5°C) o	r 45°F (7°C) or	⊿ 1°F	(5°C) + 45°F (7°C) is the cold
		t for this jurisdiction.		(0 0) 1 40 1 (7 0) 13 the cold
		RVATIONS:	Compliana	e marking must be based on
IN =		oservations)	Joinplianc	e marking must be based on
OUT =		,	Out of Co	mpliance marking must be
		n actual observations)		p
NO =			made whe	n the data item is part of the
				OR is seasonal and is not
		g at the time of the insp		
NA =		•		the data item is NOT part
	of the es	stablishment's operation	n or proced	lures)
	***		K FACTOR	_
	CDC	C RISK FACTOR - FOC	DDS FROM	I UNSAFE SOURCE
		FOOD	SOURCE	
STATUS 1. Approved Source				
IN OUT	A.	All food from Regulate prepared/canned food		ocessing Plants/ No home
IN OUT N	I ∆ R	•		urces. No recreationally
551 10	D.	caught shellfish receiv		areas. The reoreationally
IN OUT N	IN OUT NA NO C. Game, wild mushrooms harvested with approval of			
		Regulatory Authority		

DATA COLLECTION FORM (page 2 of 9)

STATUS 2. Receiving / Sound Condition

IN OUT

A. Food received at proper temperatures/ protected from contamination during transportation and receiving/food is safe, unadulterated

STATUS 3. Records

IN OUT NA NO A. Shellstock tags/labels retained for 90 days from the date the container is emptied

IN OUT NA NO B. As required, written documentation of parasite destruction maintained for 90 days for Fish products

IN OUT NA

C. CCP monitoring records maintained in accordance with HACCP plan when required

CDC RISK FACTOR-INADEQUATE COOK

PATHOGEN DESTRUCTION

STATUS 4. Proper Cooking Temperature Per Potentially Hazardous Food (PHF/TCS Food).

NOTE: Cooking temperatures must be taken to make a determination of compliance or non-compliance. Do not rely upon discussions with managers or cooks to make a determination of compliance or non-compliance. If one food item is found Out of temperature, that PHF/TCS Food category must be marked as Out of Compliance.

IN OUT NA NO A. Raw shell eggs broken for immediate service cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to155°F (68°C) for 15 seconds

IN OUT NA NO B. Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for 15 seconds

IN OUT NA NO C. Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specified 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.

DATA COLLECTION FORM (page 3 of 9)

- IN OUT NA NO D. Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds
- IN OUT NA NO E. Wild game animals cooked to $165^{\circ}F$ ($74^{\circ}C$) for 15 seconds IN OUT NA NO F. Raw animal foods cooked in microwave are rotated, stirred,

covered, and heated to 165°F (74°C). Food is allowed to stand covered for 2 minutes after cooking

IN OUT NA NO G. Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds. Specify product and temperature in the space below. NOTE: Pork observed cooked between 145°F (63°C) and 155°F (68°C), would be marked OUT here, but marked IN under Supplemental Item 17A. Please make notes in the comment section.

IN OUT NA NO H. All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds

STATUS 5. Rapid Reheating For Hot Holding

- **IN OUT NA NO** A. PHF/TCS Food that is cooked and cooled on premises is rapidly reheated to 165°F (74°C) for 15 seconds for hot holding
- **IN OUT NA NO** B. Food reheated in a microwave is heated to 165°F (74°C) or higher
- **IN OUT NA NO** C. Commercially processed ready-to-eat food, reheated to 140°F (60°C) or above **for hot holding**
- **IN OUT NA NO** D. Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters

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DATA COLLECTION FORM (page 4 of 9)

CDC RISK FACTOR - IMPROPER HOLD

LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

STATUS 6. Proper Cooling Procedure

NOTE: Record any temperature above 41°F (5°C) on blank lines. Production documents as well as statements from managers, person in charge (PIC), and employees, regarding the time the cooling process was initiated, may be used to supplement actual observations.

IN OUT NA NO A. Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6 hours

IN OUT NA NO B. PHF/TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours

IN OUT NA NO C. Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours

STATUS 7. Cold Hold 41°F (5°C)

NOTE: For the purposes of this Study, 41°F (5°C) or below will be used as the criteria for assessing <u>all</u> PHF/TCS Food that are maintained/held cold. If one product is found out of temperature the item is marked OUT of Compliance.

A. PHF/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. (Record products and temperatures in the space below.)

DATA COLLECTION FORM (page 5 of 9)

STATUS 8. Hot Hold 140°F (60°C)

IN OUT NA NO A.	PHF/TCS Food is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control. <i>NOTE: Products held between 135°F</i> (57°C) and 140°F (60°C) should be marked OUT in 8A, but IN under Supplemental Item number 18A. Record actual product
	under Supplemental Item number 18A. Record actual product and measured temperatures in the space below.

IN OUT NA NO B. Roasts are held at a temperature of 130°F (54°C) or above

STATUS 9. Time

- **IN OUT NA NO** A. Ready-to-eat PHF/TCS Food held for more than 24 hours is date marked as required (prepared on-site)
- **IN OUT NA NO** B. Discard RTE PHF/TCS Food and/or opened commercial container exceeding 7 days at < 41°F (5°C) or 4 days at < 45°F (7°C)
- **IN OUT NA NO** C. Opened Commercial container of prepared ready-to-eat PHF/TCS Food is date marked as required
- **IN OUT NA NO** D. When time only is used as a public health control, food is cooked and served within 4 hours as required

CDC RISK FACTOR-CONTAMINATED EQUIPMENT

PROTECTION FROM CONTAMINATION

STATUS 10. Separation / Segregation / Protection

- IN OUT NA NO A. Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food
- **IN OUT NA NO** B. Raw animal foods are separated from each other during storage, preparation, holding, and display
- IN OUT C. Food is protected from environmental contamination critical items
- **IN OUT** D. After being served or sold to a consumer, food is not reserved

DATA COLLECTION FORM (page 6 of 9)

STATUS 11. Food-Contact Surfaces

NOTE: This item will require some judgment to be used when marking this item IN or Out of compliance. This item should be marked Out of Compliance if observations are made that supports a pattern of non-compliance with this item. One dirty utensil, food contact surface or one sanitizer container without sanitizer would not necessarily support an Out of Compliance mark. You must provide notes concerning an Out of Compliance mark on this item.

IN OUT	 Food-contact surfaces and utensils are clean to sight and touch and sanitized before use
	CDC RISK FACTOR-POOR PERSONAL HYGIENE
	PERSONNEL
STATUS	12. Proper, Adequate Handwashing
IN OUT NO	A. Hands are clean and properly washed when and as required
STATUS	13. Good Hygienic Practices
IN OUT NO	A. Food Employees eat, drink, and use tobacco only in designated areas / do not use a utensil more than once to taste food that is sold or served / do not handle or care for animals present. 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

DATA COLLECTION FORM (page 7 of 9)

STATUS 14. Prevention of Contamination From Hands

IN OUT NA NO A. Employees do not contact exposed, ready-to-eat food with their bare hands. NOTE: In determining the status of this data item, an assessment of alternative methods when otherwise approved is to be made to determine implementation in accordance with the guidelines contained in Annex 3, 2001 Food Code, page 289.

STATUS 15. Handwash Facilities

IN OUT

A. Handwash facilities conveniently located and accessible for

employees

IN OUT B. Handwash facilities supplied with hand cleanser / sanitary

towels / hand drying devices

CDC RISK FACTOR - OTHER

FOREIGN SUBSTANCES

STATUS 16. Chemicals

IN OUT NA A. If used, only approved food or color additives. Sulfites are

not applied to fresh fruits and vegetables intended for raw

consumption

IN OUT B. Poisonous or toxic materials, chemicals, lubricants,

pesticides, medicines, first aid supplies, and other personal

care items are properly identified, stored and used

IN OUT NA C. Poisonous or toxic materials held for retail sale are properly

stored

DATA COLLECTION FORM (page 8 of 9)

SUPPLEMENTAL ITEMS

NOTE: The following items will be included as part of FDA's 2003 and 2009 data collections. These are additional items to the original 42 data item (contained in Sections 1 – 16) that were assessed as part of the original baseline.

STATUS 17. Proper Cooking Temperature (Supplement to Item 4G)

IN OUT NA NO A. Pork is cooked to 145°F (63°C) or above for 15 seconds.

NOTE: Final cooking temperatures of Pork Roasts are recorded under data item 4C.

IN OUT NA NO B. Ratites and injected meats are cooked to 155°F (68°C) for 15 seconds

STATUS 18. Hot Hold 135°F (57°C) – (Supplement to Item 8A)

IN OUT NA NO A. PHF/TCS Food is maintained at 135°F (57°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control. NOTE: Products held between 135°F (57°C) and 140°F (60°C) should be marked OUT in 8A. Record actual product and measured temperatures.

STATUS 19. Employee Health Policy

IN OUT

A. Facility has a written policy that is consistent with Section 2-201 of the Food Code for excluding and restricting employees on the basis of their health and activities as they relate to diseases that are transmissible through food. Written policy includes a statement regarding employee responsibility to notify management of symptoms and illnesses identified in the Food Code.

DATA COLLECTION FORM (page 9 of 9)

STATUS 20. Treating Juice **IN OUT NA NO** A. When packaged in a food establishment, juice is treated under a HACCP Plan to reduce pathogens or be labeled as specified in the Food Code. 21. Cooling - Raw Shell Eggs STATUS **IN OUT NA NO** A. After receiving, raw shell eggs are immediately placed under refrigeration that maintains ambient air temperature of 45°F (7°C) or less. 22. Cold Holding - Raw Shell Eggs STATUS **IN OUT NA NO** A. After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45°F (7°C) or less STATUS 23. Food & food preparation for highly susceptible populations NOTE: These items pertain specifically to those facilities that serve Highly Susceptible Populations as defined in the Food Code. Establishments would include such facility types as hospitals, nursing, homes, and elementary schools. **IN OUT NA NO** A. Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served. IN OUT NA NO B. Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served: broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls Salmonella Enteritidis. **IN OUT NA NO** C. Raw or partially cooked animal food and raw seed sprouts not served.

The following is the DATA COLLECTION FORM REFERENCE SHEET which shows the applicable *Food Code* sections under each individual data item:

REFERENCE SHEET (page 1 of 5)

1997 FDA Food Code used for Original 42 Individual Data Items

Risk Factor FOODS FROM UNSAFE SOURCES Food Source	Risk Factor INADEQUATE COOK Pathogen Destruction
1. Approved Source	4. Proper Cooking Temperature per PHF/TCS
Data Item - 1A 3-201.11* Compliance with Food Law 3-201.12* Food in A Hermetically Sealed Container. 3-201.13* Fluid Milk and Milk Products	Food <u>Data Item – 4A</u> 3-401.11(A)(1)(a)* Raw Animal Foods 3-401.11(A)(2)* Raw Animal Foods <u>Data Item – 4B</u>
Data Itom – 1P	3-401.11(A)(2)* Raw Animal Foods
3-201.14* Fish 3-201.15* Molluscan Shellfish 3-202.18* Shellstock Identification	<u>Data Item – 4C</u> 3-401.11(B)(1)(2)* Raw Animal Foods
<u>Data Item – 1C</u> 3-201.16* Wild Mushrooms	<u>Data Item – 4D</u> 3-401.11(A)(3)* Raw Animal Foods
3-201.17* Game Animals	<u>Data Item – 4E</u> 3-401.11(A)(3)* Raw Animal Foods
2. Receiving/Sound Condition	<u>Data Item – 4F</u> 3-401.12* Microwave Cooking
Data Item – 2A 3-202.11* Temperature 3-202.15* Package Integrity	<u>Data Item – 4G</u> 3-401.11(A)(2)* Raw Animal Foods
3-101.11* Safe, Unadulterated, and Honestly Presented	<u>Data Item – 4H</u> 3-401.11(A)(1)(b)* Raw Animal Foods
3. Records	5. Rapid Reheating for Hot Holding
<u>Data Item – 3A</u> 3-202.18* Shellfish Identification 3-203.12* Shellfish Maintaining Identification	Data Item 5A 3-403.11(A)* Reheating for Hot Holding
Data Item – 3B 3.402.11* Parasite Destruction 3.402.12* Records, Creation and Retention	Data Item 5B 3-403.11(B)* Reheating for Hot Holding - Microwave
<u>Data Item – 3C</u> 3-502.12* Reduced Oxygen Packaging, Criteria 8-103.12* Conformance with Approved Procedures	Data Item 5C 3-403.11(C)* Reheating for Hot Holding – Commercially Processed RTE Food
	<u>Data Item 5D</u> 3-403.11(E)* Reheating for Hot Holding –

REFERENCE SHEET (page 2 of 5)

1997 FDA Food Code used for Original 42 Individual Data Items

6. Proper Cooling Procedure	9. Time
<u>Data Item 6A</u> 3-501.14(A)* Cooling – Cooked PHF/TCS Food	Data Item 9A 3-501.17(A)(1)(2)* Ready-to-Eat, PHF/TCS Food, Date Marking – On-premises
Data Item 6B 3-501.14(B)* Cooling – PHF/TCS Food prepared from ingredients at ambient temperature	Preparation (Food is to be date marked at the time of preparation with the "consume by" date. This consume by date should include the day if preparation and is: (1) \leq 7 calendar days at 41°F (5°C) or less; or
Data Item 6C 3-501.14(C)* Cooling – PHF/TCS Food receipt of foods allowed at >41°F (5°C) during shipment	(2) ≤ 4 calendar days at 45°F (7°C)) Data Item 9B 3-501.18* Ready-to-Eat, PHF/TCS Food, Disposition
7. Cold Hold (41°F (5°C))	(Food shall be discarded if not consumed within ≤ 7 calendar days at $41^{\circ}F$ (5 °C) or less; or ≤ 4 calendar
Data Item 7A	days at $45^{\circ}F$ (7°C))
3-501.16(B)* PHF/TCS Food, Hot and Cold Holding (For the purposes of this Study, 4 °F (5 °C) or below will be used as the criteria for assessing all PHF/TCS Food that are maintained/held cold.)	Data Item 9C 3-501.17(C)* Ready-to-Eat, PHF/TCS Food, Date Marking – commercially processed food
	(Commercially processed food containers shall be clearly marked, at the time originally opened in a food establishment, with the consume by date which is, including the day the original container is opened:
8. Hot Hold (140°F (60°C))	(1) ≤ 7 calendar days at 4 °F (5 °C) or less; or
<u>Data Item 8A</u> 3-501.16(A)* PHF/TCS Food, Hot and Cold Holding	(2) ≤ 4 calendar days at 45°F (7°C)) <u>Data Item 9D</u> 3-501.19* Time as a Public Health Control
<u>Data Item 8B</u> 3-501.16(A)* PHF/TCS Food, Hot and Cold Holding	

REFERENCE SHEET (page 3 of 5)

1997 FDA Food Code used for Original 42 Individual Data Items

Risk Factor CONTAMINATED EQUIPMENT	Risk Factor POOR PERSONAL HYGIENE
Protection from Contamination	Personnel
10. Separation / Segregation /Protection	12. Proper, Adequate Handwashing
Data Item 10A 3-302.11(A)(1)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation (Separate raw animal foods from raw RTE and cooked RTE foods)	2-301.11* Clean Condition 2-301.12* Cleaning Procedure 2-301.14* When to Wash 2-301.15* Where to Wash
3-302.11(A)(2)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation (Separate raw animal foods by using separate equipment, special arrangement of food in equipment to avoid cross contamination of one type with another, or by preparing different types of food at different time or in separate areas) Data Item 10C 3-302.11(A)(4-6)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation 3-304.11(B)* Food Contact with Equipment and Utensils Data Item 10D 3-306.14(A)(B)* Returned Food, Reservice or	13. Good Hygiene Practices Data Item 13A 2-401.11* Eating, Drinking, or Using Tobacco 2-401.12* Discharges from the Eyes, Nose and Mouth 2-403.11* Handling Prohibition – Animals 3-301.12* Preventing Contamination when Tasting 14. Prevention of Contamination from Hands Data Item 14A 3-301.11* Preventing Contamination from Hands
Sale 11. Food Contact Surfaces	15. Handwash Facilities
Data Item 11A 4-601.11(A) & (B)* Equipment, Food Contact Surfaces and Utensils 4-602.11* Equipment Food-Contact Surfaces and Utensils - Frequency 4-701.10* Sanitization of Equipment and Utensils - Food Contact Surfaces and Utensils 4-702.11* Sanitization of Equipment and Utensils - Before Use After Cleaning	Data Item 15A 5-203.11* Handwashing Lavatory-Numbers and Capacity 5-204.11* Handwashing Lavatory-Location and Placement 5-205.11* Using a Handwashing Lavatory-Operation and Maintenance Data Item 15B 6-301.11 Handwashing Cleanser, Availability 6-301.12 Hand Drying Provision

REFERENCE SHEET (page 4 or 5)

1997 FDA Food Code used for Original 42 Individual Data Items

Risk Factor OTHER Chemical/Foreign Substance

16. Chemical

Data Item 16A

3-202.12* Additives

3-302.14* Protection from Unapproved Additives

(NOTE: Regarding SULFITES – Refers to any sulfites added in the food establishment, not to foods processed by a commercial processor or that come into the food establishment already on foods)

Data Item 16B

7-101.11* Identifying Information, Prominence-Original Containers

7-102.11* Common Name-Working Containers

Operational Supplies and Applications

7.201.11* Separation-Storage

7-202.11* Restriction-Presence and Use

7-202.12* Conditions of Use

7-203.11* Poisonous or Toxic Material Containers – Prohibitions

7-204.11* Sanitizers, Criteria-Chemicals

7-204.12* Chemicals for Washing Fruits and Vegetables

7-204.13* Boiler Water Additives, Criteria

7-204.14* Drying Agents, Criteria

7-205.11* Incidental Food Contact, Criteria-Lubricants

7-206.11* Restricted Use Pesticides, Criteria

7-206.12* Rodent Bait Stations

7-206.13* Tracking Powders, Pest Control and Monitoring

7-207.11* Restriction and Storage-Medicines

7-207.12* Refrigerated Medicines, Storage

7-208.11* Storage-First Aid Supplies

7-209.11* Storage-Other Personal Care Items

Data Item 16C

Stock and Retail Sale of Poisonous or Toxic Material

7.301.11* Separation-Storage and Display (Separation is to be by spacing or partitioning)

REFERENCE SHEET (page 5 of 5)

2001 FDA Food Code used for SUPPLEMENTAL DATA ITEMS

	SUPPLEMENTAL ITEMS	
17. Proper Cooking Temperature (supplement to 4G – 2005 FDA Food Code)	23. Food & Food Preparation for Highly Susceptible Populations – 2005 FDA Food Code	
Data Item 17A 3-401.11(A)(1)* Raw Animal Foods (pork)	Data Item 23A 3-801.11(A)(2)* Prohibited Foods	
Data Item 17B 3-401.11(A)(2)* Raw Animal Foods (ratites and injected meats)	Data Item 23B 3-801.11(B)* Prohibited Foods 3-801.11(E)* Prohibited Foods	
18. Hot Hold (135°F) (Supplement to 8A – 2005 FDA Food Code)	Data Item 23C 3-801.11(D)* Prohibited Foods	
Data Item 18A 3-501.16(A)(1)* PHF/TCS Food, Hot and Cold Hold	<u>LEGEND</u>	
19. Written Employee Health Policy (NOTE: 2005 FDA Food Code does not require written policy) Data Item 19A 2-201.11 Responsibility of Person in Charge 2-201.12* Exclusions and Restrictions 2-201.13 Removal of Exclusions and Restrictions 2.201.14* Responsibility of a Food Employee or an Applicant to Report to the Person in Charge 2-201.15* Reporting by the Person in Charge 2-201.15* Reporting by the Person in Charge 20. Treating Juice – 2005 FDA Food Code Data Item 20A 3-404.11 Treating Juice 21. Cooling Raw Shell Eggs – 2005 Food Code Data Item 21A 3-501.14(D)* Cooling 22. Cold Holding – Raw Shell Eggs – 2005 FDA Food Code Data Item 22A 3-501.16(B) Hot and Cold Holding	C = Celsius F = Fahrenheit RTE = Ready-to-Eat PHF = Potentially Hazardous Food TCS = Time-Temperature Control for Safety Food R.A. = Regulatory Authority	

H. Data Collection Procedure

Specialists conducted unannounced, non-regulatory inspections of the selected establishments. A representative from the state, county, or city agency having regulatory oversight over the establishments may have accompanied the Specialists. When conditions in the establishments merited regulatory actions, the accompanying state or local representative could intervene to ensure appropriate corrective actions were taken. If a state, county, or city representative was not accompanying a Specialist and conditions warranted regulatory action, the regulatory authority was contacted.

Quantitative measurements were made using equipment such as calibrated thermocouples, heat-sensitive tape, and maximum registering stem thermometers. For certain data items (see data collection form), visual observations were supplemented by asking questions of food workers and/or managers.

Using the 1997 FDA Food Code as a basis for the original 42 individual data items and the 2001 FDA Food Code and Supplement to the 2001 Food Code for the supplemental data items, the Specialists determined whether the observations made of the employee food safety practices or behaviors were IN Compliance, Out of Compliance, Not Observed, or Not Applicable.

An observation was based on an evaluation of one or more occurrences of a data item at an establishment. The Specialists were provided specific instructions for using the following four marking options:

- **IN** meant that all observed occurrences were IN Compliance with the appropriate *FDA Food Code* provision for the data item.
- OUT meant that one or more of the observations made were Out of Compliance
 with the appropriate FDA Food Code provision for the data item. An explanation
 of the specific criteria used for determining Out of Compliance for each data item
 was recorded by the Specialist on the data collection form.
- N.O. meant the data item was Not Observed during the inspection. The N.O. notation was used when a data item was a usual practice in the food establishment, but the practice was not observed during the time of the inspection. For example, if a restaurant that seasonally serves shellfish was selected for the study but the inspection occurred during non-shellfish season, then the applicable data item was marked N.O.
- N.A. meant the data item was Not Applicable. The N.A. notation was used when
 a data item was a function of the food establishment. For example, if a seafood
 department that conducts no cooking was selected for the study, then all data
 items pertaining cooking were marked N.A.

Not all four marking options were available for every individual data item. For instance, in the case of cold holding, all establishments that were included in the data collection were responsible for cold holding PHF/TCS Food. As a result, the "Not Observed"

(N.O.) and "Not Applicable" (N.A.) marking options were inappropriate given that an observation for cold holding was not only applicable in every case, but was also observable during every inspection.

The use of the "Not Observed" (N.O.) and "Not Applicable" (N.A.) as options for determining the status of individual data items was a critical component for attaining a meaningful performance indicator. For example, if the only options for marking compliance status had been IN Compliance and Out of Compliance, then the default option for data items that did not apply to an operation would have been IN Compliance. If this had been the case, the overall IN Compliance measurement for the establishment would have been higher than what was shown by actual observation of the food safety practice or employee behavior and would have been an overestimate.

Likewise, for data items that did apply to an establishment's operation, but were not observed during the inspection, the default marking option would have been IN Compliance. Again, the overall IN Compliance measurement for the establishment would have been higher than what was shown by actual observation of the food safety practice or employee behavior and would have been an overestimate.

The Specialists were provided a copy of a software program customized to store the data collected. Specialists entered the data into a database and conducted a series of quality assurance checks to verify the accuracy of the information. The data from each Specialist's software files were merged into a central database. Before analyzing the data, an additional quality assurance review of the data was conducted to ensure reporting consistency within the established project design. FDA/CFSAN/Biostatistics Branch performed the statistical analysis of the data.

I. Average Time Per Data Collection

Many regulatory agencies planning to conduct similar foodborne illness risk factor studies within their jurisdictions have requested information on data collection time for each of the facility types. During this data collection, FDA tracked the actual time spent in each of the inspected establishments. Table 6 that appears on the following page presents the average data collection time, in minutes, for each of the facility types. Travel time and off-site report preparation were not included in the FDA time assessment.

Table 6

Average Inspection Time per Establishment for each of the 9 Facility Types
(Total MINUTES per Establishment)

Facility Type	Average Inspection Time (In Minutes)
HOSPITALS	138
ELEMENTARY SCHOOLS	81
NURSING HOMES	91
FAST FOOD RESTAURANTS	73
FULL SERVICE RESTAURANTS	106
DELI	80
MEAT & POULTRY	36
SEAFOOD	41
PRODUCE	33

III. RESULTS AND DISCUSSION

The results contained in this report are intended to focus attention on foodborne illness risk factors associated with food preparation procedures and employee behaviors most in need of improvement by industry. If food safety practices within institutional foodservice, restaurants, and retail food store facility types are to be significantly improved, individuals responsible for the management and oversight of food establishments must exercise active managerial control over the risk factors. Active managerial control over risk factors requires the purposeful incorporation of actions or procedures to monitor and verify that effective controls are implemented to prevent foodborne illnesses. Food safety management systems for control of these risk factors must be an integral part of daily operations.

Reducing the occurrence of foodborne illness risk factors should be a goal for all those involved in food safety. If this goal is to be achieved, regulatory retail food program managers need to establish program performance measures that are based on reducing the occurrence of these risk factors. Regulatory inspection programs should use intervention strategies that direct the foodservice and retail food industries' efforts toward attaining active managerial control of those food safety practices and employee behaviors most likely to contribute to foodborne illness. Recommended intervention strategies for both regulatory and industry food safety professionals are presented in Section IV. Recommendations.

Presentation of the data results

The data results will be presented separately for each of the nine facility types. For each facility type, the data is presented in three parts:

- Part A. Presents the percent of observations found Out of Compliance for each risk factor
- Part B. Presents the percent of observations found Out of Compliance for individual data items that comprise the risk factor
- Part C. Summarizes the risk factors and individual data items needing priority attention

The figures presented in this section for each of the facility types include only observations of the same 42 data items used in the original 1998 baseline collection. None of the supplemental data items (Sections 17-23 of the data collection form found on pages 25-26) are included as part of the data analysis in this section. The results and discussion of the supplemental data items will be addressed later in this report in Section VI. Additional Areas of Study.

Using the Data Collection Form (Pages 18 - 26) as a reference, the data items for each risk factor are sorted using the format presented in Table 7.

Table 7

Data Collection Form – Section Reference for Risk Factors

RISK FACTOR	Number of Data Items for each Risk Factor	Referenced Sections From Data Collection Form
Food from Unsafe Sources	7	Sections 1 – 3
Inadequate Cooking	12	Sections 4 – 5
Improper Holding/Time Temperature	10	Sections 6 – 9
Contaminated Equipment/Protection from Contamination	5	Sections 10 – 11
Poor Personal Hygiene	5	Sections 12 – 15
Other (Chemical Contamination)	3	Section 16
TOTAL NUMBER OF DATA ITEMS	42	

A. <u>Percent of Observations found Out of Compliance for each RISK FACTOR</u>

Table 8

Formula for Calculating RISK FACTOR Out of Compliance Percentages

Percent Out of Compliance =

Total Number of Out of Compliance observations for the risk factor χ 100% Total Number of OBSERVATIONS (IN and OUT) for the risk factor

The percent Out of Compliance gives an indication of the overall effectiveness of existing food safety management systems for each of the risk factors for the 2008 data collection period. It can be inferred that the higher the percent Out of Compliance, the weaker the management system for control of the risk factor.

B. <u>Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor</u>

Table 9

Formula for Calculating Out of Compliance Percentages for each DATA ITEM that Comprises a Risk Factor

Percent Out of Compliance =

Total Out of Compliance Observations for the Data Item X 100%

Total number of OBSERVATIONS (IN and OUT) for the Data Item

The percent Out of Compliance for an individual data item is the proportion of establishments where that data item was Out of Compliance when the practice or procedure could be observed. Each risk factor is comprised of several individual data items based on 1997 FDA Food Code requirements. These individual data items can be used to assess in greater detail the degree of control a facility type had over each risk factor found to have a high Out of Compliance percentage.

The greater the percent Out of Compliance for an individual data item contained in a risk factor, the greater the need for improvement.

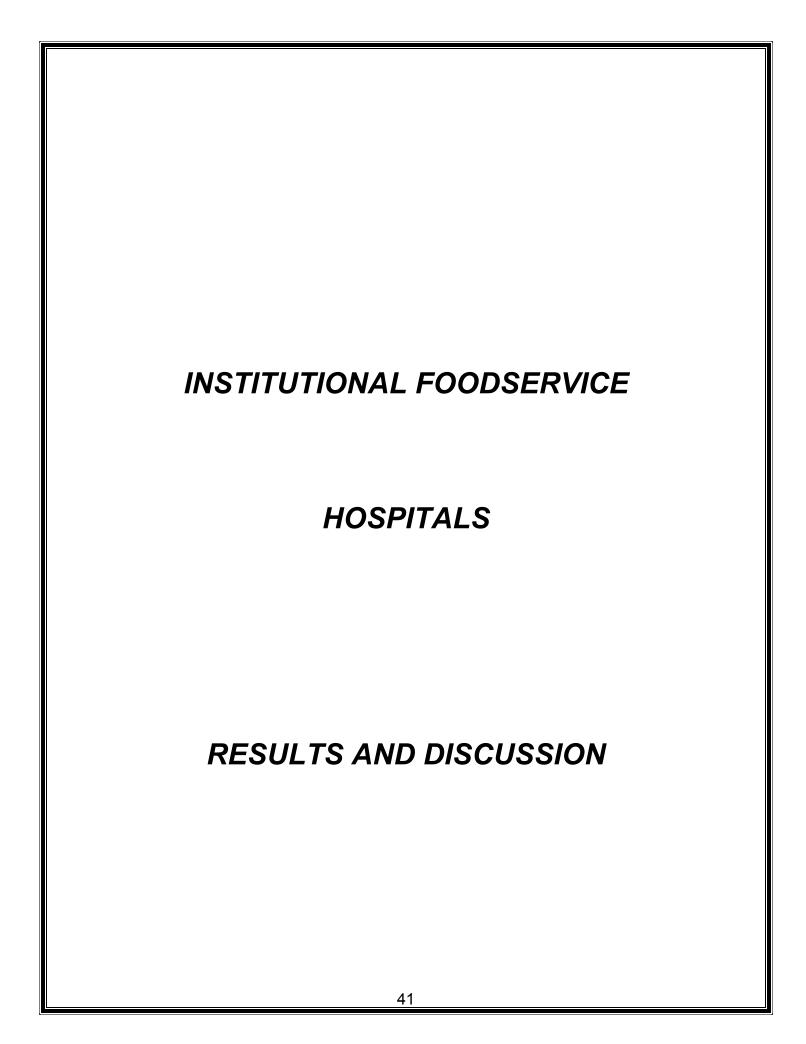
The figures in this section contain only those data items with the highest Out of Compliance percentages. In a few cases, there are one or more data items that warrant attention within a risk factor that had a relatively high overall IN Compliance percentage. For these data items, the results of the observations are addressed as discussion points rather than presented in a bar graph format. The results for all data items are available in Appendices A - I.

C. <u>Summary of foodborne illness RISK FACTORS and INDIVIDUAL</u> DATA ITEMS in need of priority attention

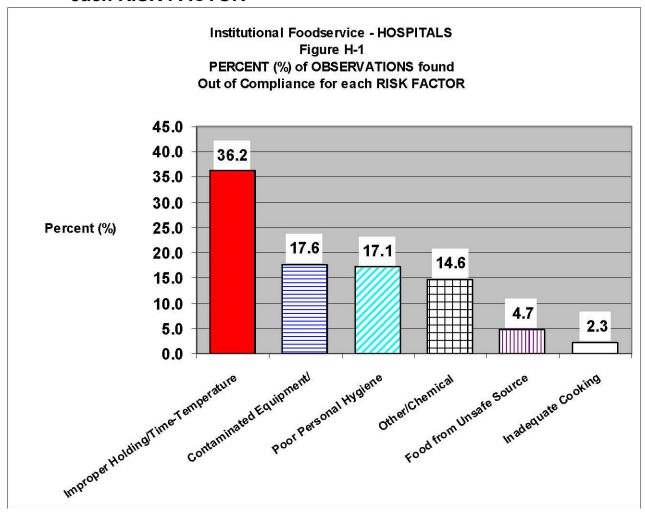
Section C summarizes the foodborne illness risk factors and individual data items (i.e., food safety practices and behaviors) in need of priority attention suggested by the data presented in parts A and B. Those risk factors and data items with the most significant Out of Compliance percentages based on the 2008 data collection are presented in the summary section.

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A. Percent of observations found Out of Compliance for each RISK FACTOR



FOODBORNE ILLNESS RISK FACTOR		Total Obs. (IN & OUT)	% OUT
Improper Holding/Time & Temperature	175	483	36.2%
Contaminated Equipment/Protection from Contamination	78	443	17.6%
Poor Personal Hygiene	77	449	17.1%
Other/Chemical	14	96	14.6%
Food From Unsafe Sources	9	193	4.7%
Inadequate Cooking	5	222	2.3%

Discussion for Figure H-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Contaminated equipment/protection from contamination, poor personal hygiene, and chemical contamination also had notable Out of Compliance percentages. Management systems that were implemented to ensure foods were adequately cooked and from safe sources appeared to be effective during this data collection period.

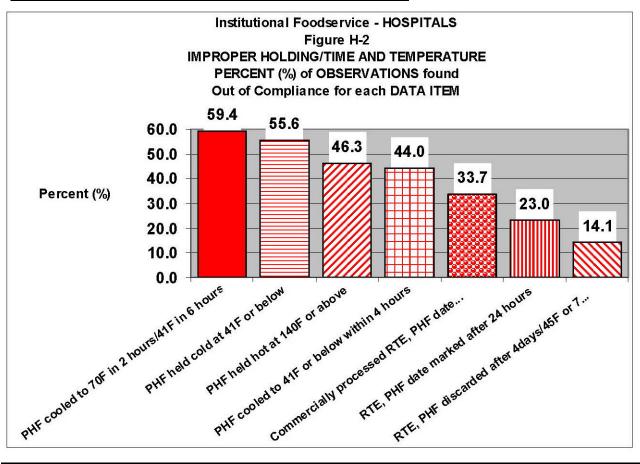
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

For hospitals, the foodborne illness risk factors most in need of attention with their corresponding Out of Compliance percentages are as follows:

- Improper Hold/Time and Temperature (36.2%)
- Contaminated Equipment/Protection from Contamination (17.6%)
- Poor Personal Hygiene (17.1%)
- Other/Chemical (14.6%)

Figures H-2 through H-4 provide a breakdown for the first three of these risk factors into data items that represent specific food preparation procedures and employee behaviors in need of attention. These figures provide insight into the relative strengths and weaknesses of the food safety management systems in place in hospitals to control each of the risk factors during the 2008 data collection.

The other/chemical risk factor had one data item within this risk factor of interest. A summary of the results of the Out of Compliance observations for the identification, storage, and use of chemicals/toxic materials data item is presented as a part of the discussion.



	DATA ITEM	#OUT	Total Obs. (IN & OUT)	% OUT
	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours	19	32	59.4%
	PHF/TCS Food held cold at 41°F or below	50	90	55.6%
	PHF/TCS Food held hot at 140°F or above	37	80	46.3%
	PHF/TCS Food (prepared from ingredients at ambient temp.) cooled to 41°F or below within 4 hours	11	25	44.0%
	Commercially-processed, RTE, PHF/TCS Food date marked	28	83	33.7%
	RTE, PHF/TCS Food date marked after 24 hours	20	87	23.0%
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F	10	71	14.1%
*	Roasts are held at a temperature of 130°F or above*	0	6	*
*	Foods received at temperatures according to Law are cooled to 41°F within 4 hours*	0	9	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0	0	*

^{*} These three Improper Holding/Time & Temperature Data Items do not appear in Figure H-2 due to a low number of total observations (obs.)

Discussion for Figure H-2

The data items, with their corresponding Out of Compliance percentages, for the improper holding/time and temperature risk factor that are most in need of attention include the following:

- Cooling of cooked or reheated PHF/TCS Food (59.4%)
- Maintaining cold holding temperatures for PHF/TCS Food (55.6%)
- Maintaining hot holding temperatures for PHF/TCS Food (46.3%)
- PHF/TCS Food (prepared from ingredients at ambient temperature) cooled to 41°F or below within 4 hours (44.0%)
- Date marking of open containers of commercially-processed, ready-to-eat PHF/TCS Food (33.7%)
- Date marking ready-to eat PHF/TCS Food made on-site (23.0%)
- Discarding RTE, PHF/TCS Food after they have exceeded time/temperature storage limits (14.1%)

Cooling of PHF/TCS Food

Safe cooling requires the removal of heat from foods quickly enough to prevent the growth of spore-forming pathogens. Paragraph 2-103.11(G) of the 1997 Food Code specifically identifies cooling as a process that requires daily management oversight of the employees' use of good cooling methods and routine monitoring of food temperatures. This is increasingly important as reduced oxygen packaging such as cook-chill and sous vide processing come into wider use. Hospital foodservice directors and managers need to closely monitor cooling to ensure their practices and procedures are effective in rapidly cooling PHF/TCS Food.

The total number of observations for cooling was substantially less than the total number of observations for other data items. The time of day the data was collected and the length of the time available to spend in a facility were significant factors limiting the number of observations of cooling. In some situations, for example, as much as six hours may be required on-site to document compliance with the *FDA Food Code* critical limits for cooling. Nonetheless, observations made of cooked or reheated PHF/TCS Food during cooling had the highest Out of Compliance percentage. In addition, the percent Out of Compliance for cooling PHF/TCS Food from ambient temperature ingredients is also of interest, and procedures for this process should be evaluated to ensure that food safety controls are in place.

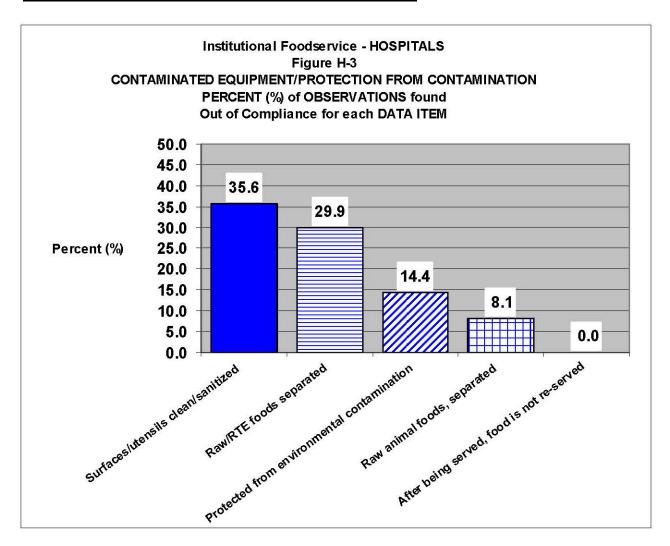
Cold and Hot Holding of PHF/TCS Food

Holding PHF/TCS Food at the proper cold or hot temperatures is critical to preventing the growth of bacteria. The percent Out of Compliance for hot holding and cold holding are high at 46.3% and 55.6%, respectively. Equipment; processes, and monitoring procedures related to maintaining temperature control for PHF/TCS Food need to be assessed, and corrective actions should be taken when necessary.

Date Marking

Date marking of refrigerated ready-to-eat, PHF/TCS Food is an important food safety management system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF/TCS Food that has remained in cold storage beyond the parameters described in the *FDA Food Code* prevents foods with a harmful level of *Listeria monocytogenes* from being sold or served. It is especially important to date mark ready-to-eat, PHF/TCS food in hospitals because the meals are primarily served to a highly susceptible population. Control of cold holding temperatures and date marking provide interlocking protection by slowing the growth of *Listeria monocytogenes* and establishing a time limit for discarding food before the organism can multiply to dangerous levels.

When cooling, cold holding, and date marking are viewed in the context of a total food safety management system, the potential for bacterial growth increases with each uncontrolled process step. It is essential that each process step be routinely monitored in a manner that enables management to take prompt corrective action before an unsafe product reaches the consumer.



DATA ITEM		Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	32	90	35.6%
Raw/RTE foods, separated	26	87	29.9%
Protected from environmental contamination	13	90	14.4%
Raw animal food, separated	7	86	8.1%
After being served, food is not re-served	0	90	0.0%

Discussion for Figure H-3

The food safety procedures for the contaminated equipment/protection from contamination risk factor that are most in need of attention include the following:

- Cleaning and sanitizing food-contact surfaces and utensils (35.6%)
- Separating raw animal foods from ready-to-eat foods (29.9%)
- Protecting from environmental contamination (14.4%)

Cleaning and Sanitizing

Proper cleaning and sanitization of food-contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and clean-in-place equipment such as slicers and mixers are cleaned and sanitized between uses.

Paragraph 2-103.11(I) of the 1997 Food Code addresses the manager's responsibility for ensuring that employees routinely monitor all aspects of the sanitizing process for multiuse equipment and utensils. The high Out of Compliance percentage for cleaning and sanitizing food-contact surfaces and utensils indicates a weakness in hospital foodservice management systems designed to prevent cross-contamination.

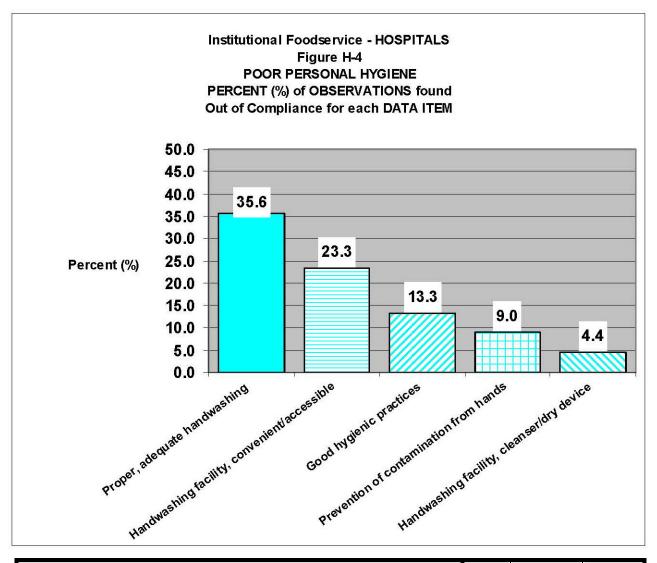
Separation of Raw Animal Foods from Ready-to-Eat Foods

Raw animal foods are a potential source of contamination in any food operation. Storing raw animal foods above or in close proximity to ready-to-eat foods increases the potential for food to become contaminated. Having organized, designated areas for the safe storage of raw animal products will help prevent cross-contamination of cooked and ready-to-eat foods.

Preventing cross-contamination between raw animal foods and ready-to-eat foods extends to the food preparation area. Designated, separate food preparation areas should be provided for raw and ready-to-eat products. If common preparation areas must be used, then procedures must be in place to ensure proper cleaning and sanitizing between uses.

Protected from Environmental Contamination

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, condensate waste, or chemicals. These contaminates may be introduced by other products or equipment stored in close proximity or by persons who are delivering, stocking, or opening packages. Foodservice managers need to ensure that standard operating procedures are in place to protect food from environmental contamination from the moment it is received until it is served or sold to the consumer. Except during cooling, stored products should be covered or wrapped to prevent the entry of microbes and other contaminants.



DATA ITEM		Total Obs. (IN & OUT)	
Proper, adequate handwashing	32	90	35.6%
Handwashing facility, convenient/accessible	21	90	23.3%
Good hygienic practices	12	90	13.3%
Prevention of contamination from hands	8	89	9.0%
Handwashing facility, cleanser/drying device	4	90	4.4%

Discussion for Figure H-4

The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include the following:

- Proper, adequate handwashing (35.6%)
- Convenient and accessible handwashing facilities (23.3%)
- Good hygienic practices (13.3%)

Proper, Adequate Handwashing/Handwashing Facilities

Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom, or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities and/or supplies of hand cleanser/drying devices may contribute to the lack of proper handwashing. Also, the temporary placement of mobile equipment in front of a hand sink and the use of handwashing facilities for other purposes can limit employee access and discourage handwashing. Paragraph 2-103.11(D) of the 1997 Food Code specifically addresses manager's responsibility to routinely monitor the effectiveness of employee handwashing. Reinforcing the importance of handwashing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of handwashing practices.

Good Hygienic Practices

Proper hygienic practices by food employees minimize the possibility of transmitting illness through food. Employee practices such as eating, drinking, and smoking in food preparation areas and working while experiencing persistent coughing and sneezing must be prohibited. Elimination of these practices will help prevent the transfer of microorganisms to foods and food-contact surfaces.

Discussion for the Other/Chemical Risk Factor

Table 10

Assessment of the Other/Chemical Category – HOSPITALS

Poisonous or Toxic Materials are Properly Identified, Stored, and Used

13	90	14.4%

Thirteen out of the fourteen Out of Compliance observations relating to the other/chemical risk factor are attributed to one data item. The proper identification, storage, and use of cleaners, sanitizers, and other chemicals in hospitals are in need of attention. Food safety procedures related to the identification, storage, and use of cleaners, sanitizers, and other chemicals need to be reviewed and revised, if necessary, to address any gaps in the program that may be contributing to the Out of Compliance observations made for this data item.

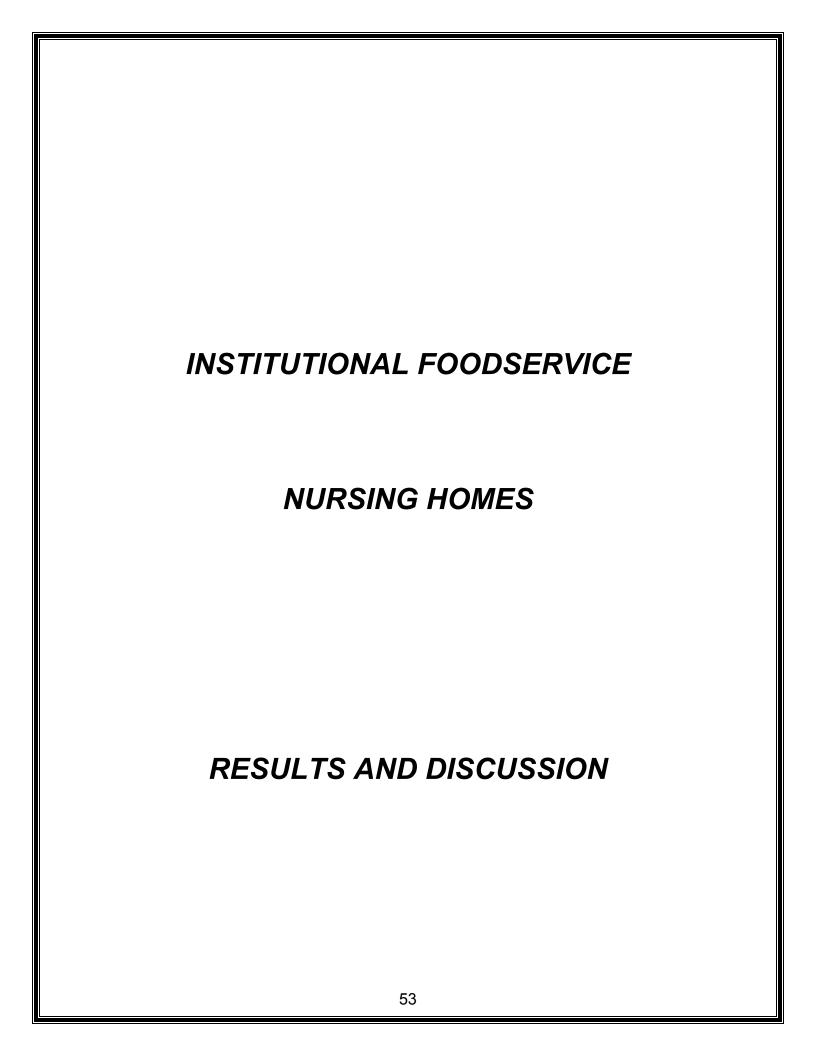
C. Summary of Foodborne Illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention.

Table 11

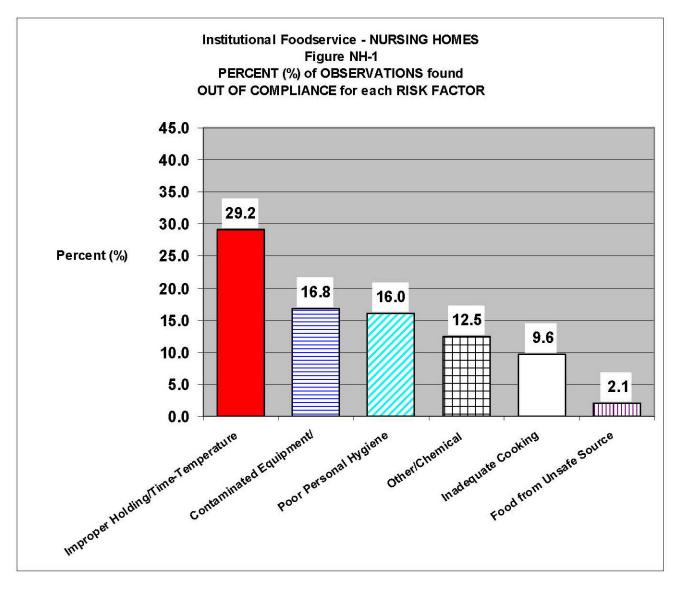
Institutional Foodservice - HOSPITALS

Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)
	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours
	PHF/TCS Food held cold at 41°F or below
Improper Holding/ Time & Temperature	PHF/TCS Food held hot at 140°F or above
	PHF/TCS Food (prepared from ingredients at ambient temperature) cooled to 41°F or below within 4 hours
	Commercially-processed RTE, PHF/TCS Food date marked
	RTE PHF/TCS Food date marked after 24 hours
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F
Contaminated Equipment/	Surface/Utensils cleaned/sanitized
Protection from Contamination	Raw animal foods separated from RTE foods
	Protection from environmental contamination
	Proper, adequate handwashing
Poor Personal Hygiene	Handwashing facility, convenient/accessible
	Good hygienic practices
Other/Chemical	Poisonous or toxic materials are properly identified, stored, and used



A. Percent of observations found Out of Compliance for each RISK FACTOR



FOODBORNE ILLNESS RISK FACTOR		Total Obs. (IN & OUT)	% OUT
Improper Holding/Time & Temperature	141	483	29.2%
Contaminated Equipment/Protection from Contamination	77	459	16.8%
Poor Personal Hygiene	73	455	16.0%
Other/Chemical	12	96	12.5%
Inadequate Cooking	16	166	9.6%
Food From Unsafe Sources	4	192	2.1%

Discussion For Figure NH-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Contaminated equipment/protection from contamination, poor personal hygiene, and chemical contamination also had notable Out of Compliance percentages. Management systems that were implemented to ensure foods were adequately cooked and from safe sources appeared to be effective during this data collection period.

B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

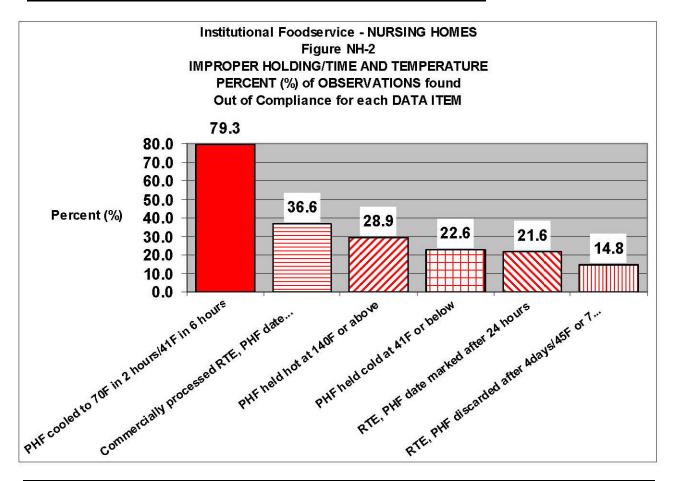
For nursing homes, the foodborne illness risk factors most in need of attention with their corresponding Out of Compliance percentages are as follows:

- Improper Holding/Time and Temperature (29.2%)
- Contaminated Equipment/Protection from Contamination (16.8%)
- Poor Personal Hygiene (16.0%)
- Other/Chemical (12.5%)

Figures NH-2 through NH-4 provides a breakdown of the first three of these risk factors into data items that represent specific food preparation procedures and employee behaviors in need of attention. These figures provide insight into the relative strengths and weaknesses of the food safety management systems in place in nursing homes to control each of the risk factors during the 2008 data collection.

The other/chemical risk factor had one data item of interest. A summary of the results of the Out of Compliance observations for the identification, storage, and use of chemicals/toxic materials data item is presented as part of the discussion.

Institutional Foodservice - NURSING HOMES



	DATA ITEM	#OUT	Total Obs. (IN & OUT)	% OUT
	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours	23	29	79.3%
	Commercially-processed, RTE, PHF/TCS Food date marked	30	82	36.6%
	PHF/TCS Food held hot at 140°F or above	22	76	28.9%
	PHF/TCS Food held cold at 41°F or below	21	93	22.6%
	RTE, PHF/TCS Food date marked after 24 hours	19	88	21.6%
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F	12	81	14.8%
*	PHF/TCS Food (prepared from ingredients at ambient temp.) is cooled to 41°F within 4 hours*	12	19	*
*	Roasts are held at temperature of 130°F or above*	1	4	*
*	Foods received at temperatures according to Law are cooled to 41°F within 4 hours.	1	11	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0	0	*

^{*} These four Improper Holding/Time & Temperature Data Items do not appear in Figure NH-2 due to a low number of total observations (obs.)

Discussion for Figure NH-2

For the improper holding/time and temperature risk factor, there is a need to review food safety systems related to:

- Cooling of cooked or reheated PHF/TCS Food (79.3%)
- Date marking of open containers of commercially-processed ready-to-eat PHF/TCS Food (36.6%)
- Maintaining hot holding temperatures for PHF/TCS Food (28.9%)
- Maintaining cold holding temperatures for PHF/TCS Food (22.6%)
- Date marking ready-to-eat PHF/TCS Food made on site (21.6%)
- Discarding RTE, PHF/TCS Food after they have exceeded time/temperature storage limits (14.8%)

Cooling of PHF/TCS Food

Safe cooling requires the removal of heat from foods quickly enough to prevent the growth of spore-forming pathogens. Section 2-103.11(G) of the *Food Code* specifically identifies cooling as a process which requires daily management oversight of the employees' use of effective cooling methods and routine monitoring of food temperatures during cooling. Nursing home foodservice directors and managers need to closely monitor cooling to ensure their practices and procedures are effective in rapidly cooling PHF/TCS Food.

The total number of observations for cooling was substantially less than the total number of observations for other data items. The time of day the data was collected and the length of the time available to spend in a facility were significant factors limiting the number of observations of cooling. For example, as much as six hours may be required on-site to document compliance with the *FDA Food Code* critical limits for cooling. Nevertheless, taking the limited number of observations into account, the high Out of Compliance percentage for cooling foods that have been cooked or reheated seem to warrant more focused attention on ensuring control of this food safety procedure.

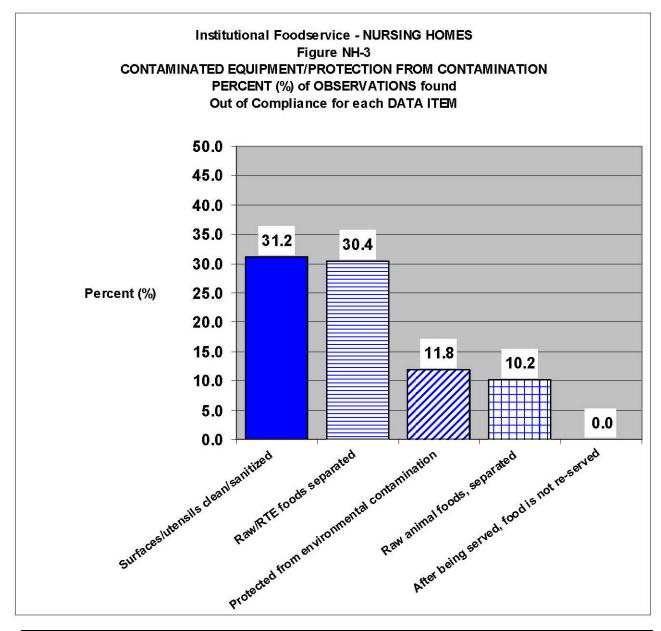
Date Marking

Date marking of refrigerated ready-to-eat, PHF/TCS Food is an important food safety management system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF/TCS Food that has remained in cold storage beyond the parameters described in the *FDA Food Code* prevents foods with a harmful level of *Listeria monocytogenes* from being served. It is especially important to date mark ready-to-eat, PHF/TCS food in nursing homes because the meals are primarily served to a highly susceptible population.

Cold and Hot Holding of PHF/TCS Food

Holding PHF/TCS Food at the proper cold or hot temperatures is critical to preventing the growth of bacteria. Equipment, processes, and monitoring procedures related to maintaining temperature control for PHF/TCS Food need to be assessed, and corrective action should be taken if necessary. Control of cold holding temperatures and date marking provide interlocking protection by slowing the growth of *Listeria monocytogenes* and establishing a time limit for discarding food before the organism can multiply to dangerous levels.

When cooling, cold holding, and date marking are viewed in the context of a total food safety system, the potential for bacterial growth increases with each uncontrolled process step. It is essential that each process step be routinely monitored in a manner that enables management to take prompt corrective action before an unsafe product reaches the consumer.



DATA ITEM		Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	29	93	31.2%
Raw/RTE foods, separated	28	92	30.4%
Protected from environmental contamination	11	93	11.8%
Raw animal food, separated	9	88	10.2%
After being served, food is not re-served	0	93	0.0%

Institutional Foodservice - NURSING HOMES

Discussion for Figure NH-3

The food safety procedures for the contaminated equipment/protection from contamination risk factor that are most in need of attention include the following:

- Cleaning and sanitizing food-contact surfaces and utensils (31.2%)
- Separating raw animal foods from ready-to-eat foods (30.4%)

Cleaning and Sanitizing

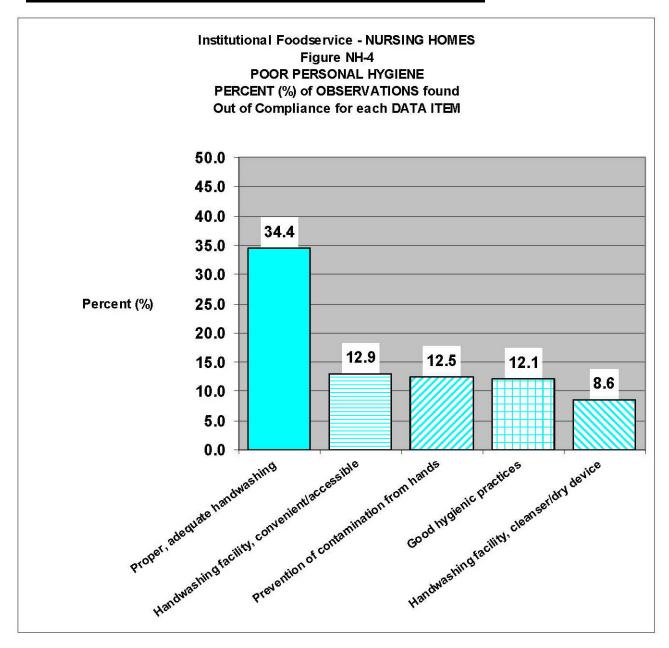
Proper cleaning and sanitization of food-contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and clean-in-place equipment such as slicers and mixers are cleaned and sanitized between uses.

The high Out of Compliance percentage for cleaning and sanitizing food-contact surfaces and utensils indicates a weakness in nursing home foodservice management systems designed to prevent cross-contamination.

Separation of Raw Animal Foods from Ready-to-Eat Foods

Raw animal foods are a potential source of contamination in any food operation. Storing raw animal foods above or in close proximity to ready-to-eat foods increases the potential for food to become contaminated. To prevent cross-contamination, raw animal foods should also be separated by species based on required minimum cooking temperatures. Required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters may vary with different types of raw animal foods. Having organized, designated areas for the safe storage of raw animal products will help prevent cross-contamination of foods.

Preventing cross-contamination between raw animal foods and ready-to-eat foods extends to the food preparation area. Designated, separate food preparation areas should be provided for raw and ready-to-eat products. If common preparation areas must be used, then procedures must be in place to ensure proper cleaning and sanitizing between uses.



DATA ITEM		#OUT	Total Obs. (IN & OUT)	% OUT
	Proper, adequate handwashing	31	90	34.4%
	Handwashing facility, convenient/accessible	12	93	12.9%
	Prevention of contamination from hands	11	88	12.5%
	Good hygienic practices	11	91	12.1%
	Handwashing facility, cleanser/drying device	8	93	8.6%

Discussion for Figure NH-4

The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include the following:

- Proper, adequate handwashing (34.4%)
- Convenient and accessible handwashing facilities (12.9%)
- Prevention of contamination from hands (12.5%)
- Good hygienic practices (12.1%)

Proper, Adequate Handwashing/Handwashing Facilities

Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom, or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities and/or supplies of hand cleanser/drying devices may contribute to a lack of proper handwashing. Also, the temporary placement of mobile equipment in front of the hand sink and the use of handwashing facilities for other purposes can limit employee access and discourage handwashing. Paragraph 2-103.11(D) of the 1997 Food Code specifically addresses the manager's responsibility to routinely monitor the effectiveness of employee handwashing. Reinforcing the importance of handwashing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of handwashing practices.

Prevention of Contamination From Hands

Handwashing alone may not prevent the transmission of pathogens to foods via hand contact; therefore, preventing bare hand contact with ready-to-eat foods is an essential control measure for limiting the spread of harmful bacteria and viruses from the hands to ready-to-eat food. Reinforcing the importance of preventing bare hand contact with ready-to-eat foods should be supported by a management system that includes proper employee training, the use of utensils and/or gloves, and the monitoring of practices to identify to what extent procedures are being followed.

Good Hygienic Practices

Proper hygienic practices by food employees minimize the possibility of transmitting disease through food. Employee practices such as eating, drinking and smoking in food preparation areas and working while experiencing persistent coughing and sneezing must be prohibited. Elimination of these practices will help prevent the transfer of microorganisms to foods and food-contact surfaces.

Discussion of the Other/Chemical Risk Factor

Table 12

Assessment of the Other/Chemical Category – NURSING HOMES

Poisonous or Toxic Materials are Properly Identified, Stored, and Used

12	93	12.9%

All of the Out of Compliance observations relating to the other/chemical risk factor are attributed to one data item. The proper identification, storage, and use of cleaners, sanitizers, and other chemicals in nursing homes are in need of attention. Food safety procedures related to the identification, storage, and use of cleaners, sanitizers, and other chemicals need to be reviewed and revised, if necessary, to address any gaps in the program that may be contributing to the Out of Compliance observations of this data item.

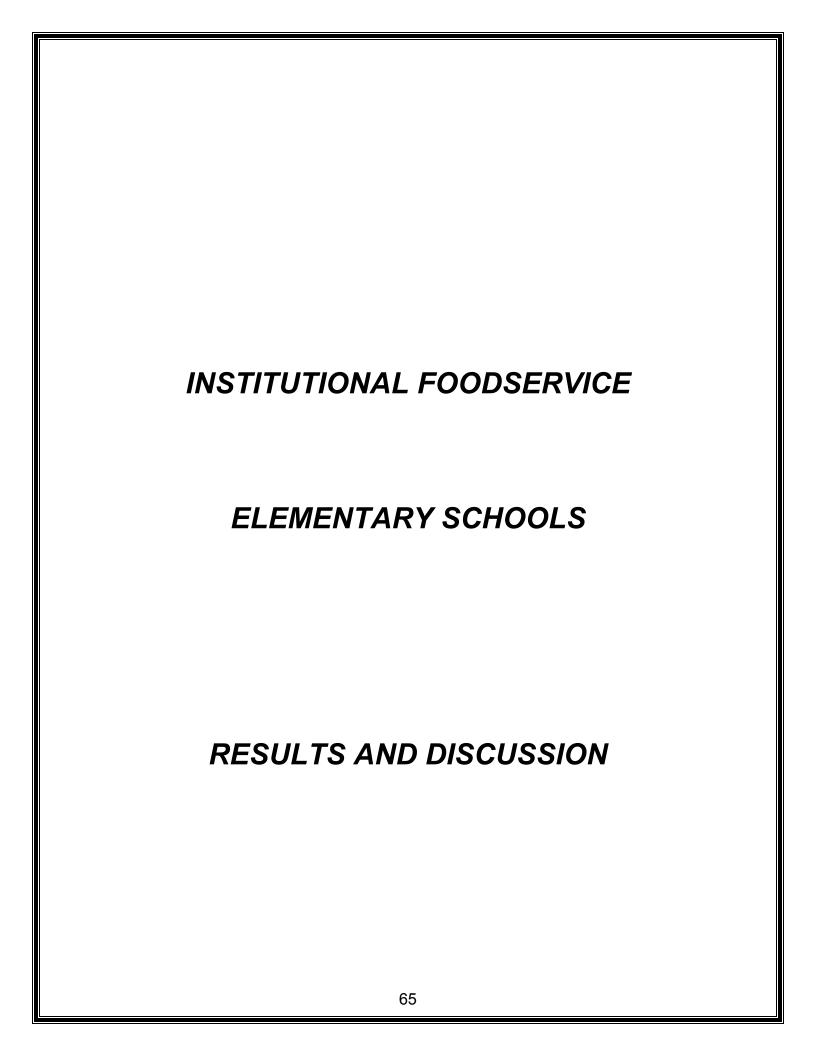
C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

Table 13

Institutional Foodservice – NURSING HOMES

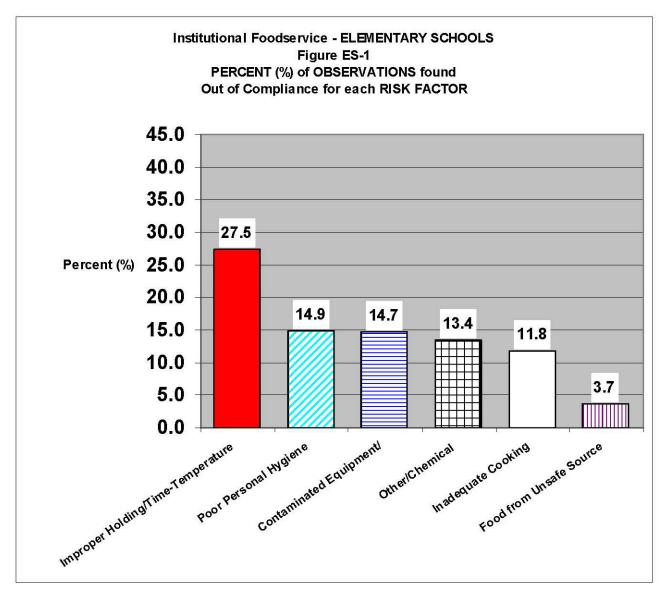
Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of priority attention (From Section B)		
	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours		
	Commercially-processed RTE, PHF/TCS Food date marked		
Improper Holding/ Time & Temperature	PHF/TCS Food held hot at 140°F or above		
Time & Temperature	PHF/TCS Food held cold at 41°F or below		
	RTE PHF/TCS Food date marked after 24 hours		
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F		
Contaminated Equipment/	Surface/Utensils cleaned/sanitized		
Protection from Contamination	Raw animal foods separated from RTE foods		
	Proper, adequate handwashing		
Poor Porconal Lygiana	Handwashing facility convenient/accessible		
Poor Personal Hygiene	Prevention of contamination from hands		
	Good hygienic practices		
Other/Chemical	ther/Chemical Poisonous or toxic materials properly identified, stored, and used		



Institutional Foodservice - ELEMENTARY SCHOOLS

A. Percent of observations found Out of Compliance for each RISK FACTOR



FOODBORNE ILLNESS RISK FACTOR		# OUT	Total Obs. (IN & OUT)	% OUT
	Improper Holding/Time & Temperature	100	364	27.5%
	Poor Personal Hygiene	69	463	14.9%
	Contaminated Equipment/ Protection from Contamination	50	339	14.7%
	Other/Chemical	13	97	13.4%
	Inadequate Cooking	9	76	11.8%
	Food from Unsafe Sources	7	187	3.7%

Institutional Foodservice – ELEMENTARY SCHOOLS

Discussion for Figure ES-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Poor personal hygiene, contaminated equipment/protection from contamination, chemical contamination also had notable Out of Compliance percentages. Management systems that were implemented to ensure foods were adequately cooked and from safe sources appeared to be effective during this data collection period.

B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

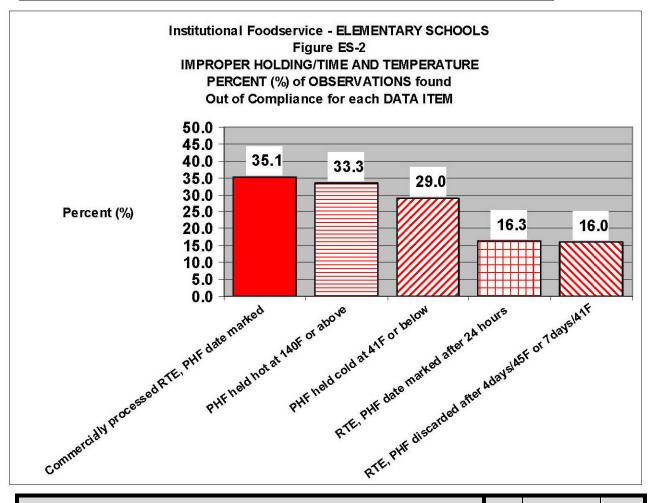
For elementary schools, the foodborne illness risk factors most in need of attention and their corresponding Out of Compliance percentages are as follows:

- Improper Holding/Time and Temperature (27.5%)
- Poor Personal Hygiene (14.9%)
- Contaminated Equipment/Protection from Contamination (14.7%)
- Other/Chemical (13.4%)

Figures ES-2 through ES-4 provides a breakdown of the first three of these risk factors into data items that represent specific food preparation procedures and employee behaviors in need of attention. These figures provide insight into the relative strengths and weaknesses of the food safety management systems in place in elementary schools to control each of the risk factors during the 2008 data collection.

The other/chemical risk factor had one data item of interest. A summary of the results of the Out of Compliance observations for the identification, storage, and use of chemicals/toxic materials data item is presented as part of the discussion.

<u>Institutional Foodservice – ELEMENTARY SCHOOLS</u>



	DATA ITEM		Total Obs. (IN & OUT)	% OUT
	Commercially-processed, RTE, PHF/TCS Food date marked	20	57	35.1%
	PHF/TCS Food held hot at 140°F or above	26	78	33.3%
	PHF/TCS Food held cold at 41°F or below	27	93	29.0%
	RTE, PHF/TCS Food date marked after 24 hours	8	49	16.3%
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F	8	50	16.0%
*	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours*	3	5	*
*	PHF/TCS Food (prepared from ingredients at ambient temp.) is cooled to 41°F or below within 4 hours*	7	16	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	1	5	*
*	Foods received at temperatures according to Law are cooled to 41°F within 4 hours*	0	11	*
*	Roasts are held at a temperature of 130°F or above*	0	0	*

^{*} These five Improper Holding/Time & Temperature Data Items do not appear in Figure ES-2 due to a low number of total observations (obs.)

Institutional Foodservice – ELEMENTARY SCHOOLS

Discussion for Figure ES-2

For the improper holding/time and temperature risk factor, there is a need to review food safety management systems related to:

- Date marking of open containers of commercially-processed, ready-to-eat PHF/TCS Food (35.1%)
- Maintaining hot holding temperatures for PHF/TCS Food (33.3%)
- Maintaining cold holding temperatures for PHF/TCS Food (29.0%)
- Date marking ready-to eat, PHF/TCS Food made on site (16.3%)
- Discarding RTE, PHF/TCS Food after they have exceeded time/temperature storage limits (16.0%)

Date Marking

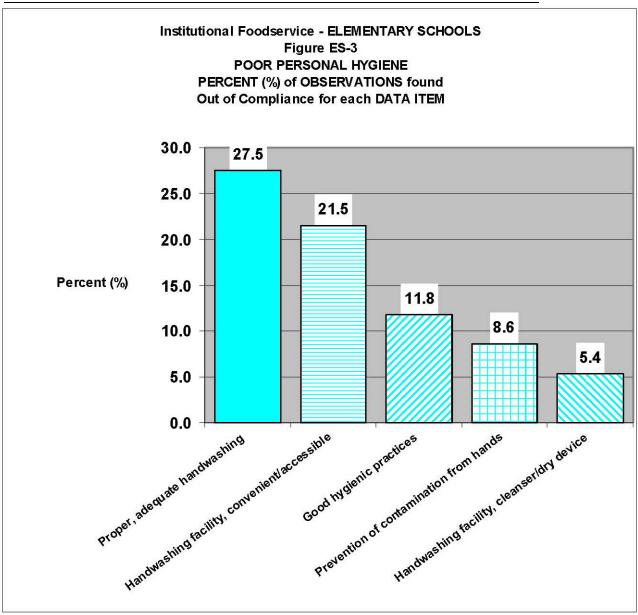
Date marking of refrigerated ready-to-eat, PHF/TCS Food is an important food safety management system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF/TCS Food that has remained in cold storage beyond the parameters described in the *Food Code* prevents foods with a harmful level of *Listeria monocytogenes* from being served.

Cold and Hot Holding of PHF/TCS Food

Holding PHF/TCS Food at the proper hot or cold temperatures is critical to preventing the growth of bacteria. Equipment, processes, and monitoring procedures related to maintaining temperature control for PHF/TCS Food need to be assessed, and corrective action should be taken if necessary. Control of cold holding temperatures and date marking provide interlocking protection by slowing the growth of *Listeria monocytogenes* and establishing a time limit for discarding food before the organism can multiply to dangerous levels.

When cooling, cold holding, and date marking are viewed in the context of a total food safety system, the potential for bacterial growth increases with each uncontrolled process step. It is essential that each process step be routinely monitored in a manner that enables the manager to take prompt corrective actions before an unsafe product reaches the consumer.

<u>Institutional Foodservice – ELEMENTARY SCHOOLS</u>



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	Proper, adequate handwashing	25	91	27.5%
	Handwashing facility, convenient/accessible	20	93	21.5%
	Good hygienic practices	11	93	11.8%
	Prevention of contamination from hands	8	93	8.6%
_	Handwashing facility, cleanser/drying device	5	93	5.4%

Institutional Foodservice – ELEMENTARY SCHOOLS

Discussion for Figure ES-3

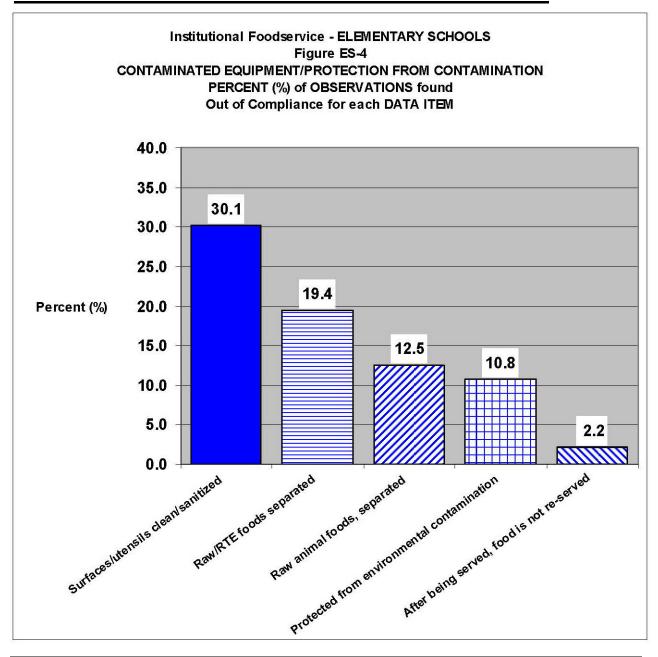
The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include the following:

- Proper, adequate handwashing (27.5%)
- Convenient and accessible handwashing facilities (21.5%)

Proper, Adequate Handwashing/Handwashing Facilities

Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom, or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities and/or supplies of hand cleanser/drying devices may contribute to a lack of proper handwashing. Also, the temporary placement of mobile equipment in front of the hand sink and the use of handwashing facilities for other purposes can limit employee access and discourage handwashing. Paragraph 2-103.11(D) of the 1997 Food Code specifically addresses the manager's responsibility to routinely monitor the effectiveness of employee handwashing. Reinforcing the importance of handwashing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of handwashing practices.

<u>Institutional Foodservice – ELEMENTARY SCHOOLS</u>



DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	28	93	30.1%
Raw/RTE foods, separated	7	36	19.4%
Raw animal foods, separated	3	24	12.5%
Protected from environmental contamination	10	93	10.8%
After being served, food is not re-served	2	93	2.2%

Institutional Foodservice – ELEMENTARY SCHOOLS

Discussion for Figure ES-4

The food safety procedures for the contaminated equipment/protection from contamination risk factor that are most in need of attention include the following:

- Cleaning and sanitizing food-contact surfaces and utensils (30.1%)
- Separating raw animal foods from ready-to-eat foods (19.4%)
- Separating raw animal foods (12.5%)

Cleaning and Sanitizing

Proper cleaning and sanitization of food-contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and clean-in-place equipment such as slicers and mixers are cleaned and sanitized between uses.

Paragraph 2-103.11(I) of the 1997 Food Code addresses the manager's responsibility for ensuring that employees routinely monitor all aspects of the sanitizing process for multiuse equipment and utensils. The high Out of Compliance percentage for cleaning and sanitizing food-contact surfaces and utensils indicates a weakness in elementary school foodservice management systems designed to prevent cross-contamination.

Separation of Raw Animal Foods from Ready-to-Eat Foods

Raw animal foods are a potential source of contamination in any food operation. Storing raw animal foods above or in close proximity to ready-to-eat foods increases the potential for food to become contaminated. To prevent cross-contamination, raw animal foods should also be separated by species based on required minimum cooking temperatures. Required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters may vary with different types of raw animal foods. Having organized, designated areas for the storage of different types of raw animal products will help prevent cross-contamination of foods.

Preventing cross-contamination between raw animal foods and ready-to-eat foods extends to the food preparation area. Designated, separate food preparation areas should be provided for raw and ready-to-eat products. If common preparation areas must be used, then procedures must be in place to ensure proper cleaning and sanitizing between products.

<u>Institutional Foodservice – ELEMENTARY SCHOOLS</u>

Discussion for the Other/Chemical Risk Factor

Table 14

Assessment of the Other/Chemical Category – ELEMENTARY SCHOOLS

Poisonous or Toxic Materials are Properly Identified, Stored, and Used

13	93	14.0%

All of the Out of Compliance observations relating to the other/chemical risk factor were attributed to one data item. The proper identification, storage, and use of cleaners, sanitizers, and other chemicals in elementary schools are in need of attention. Food safety procedures related to the identification, storage, and use of cleaners, sanitizers, and other chemicals need to be reviewed and revised, if necessary, to address any gaps in the program that may be contributing to the high Out of Compliance percentage.

Institutional Foodservice - ELEMENTARY SCHOOLS

C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

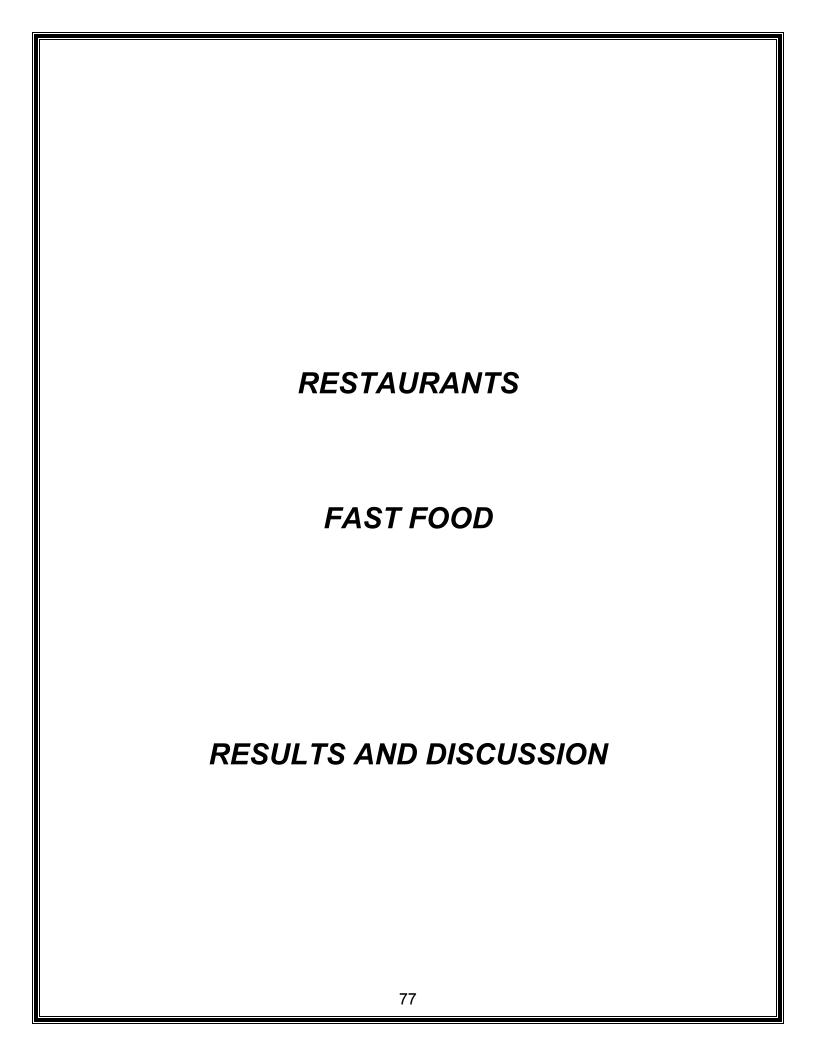
Table 15

Institutional Foodservice – ELEMENTARY SCHOOLS

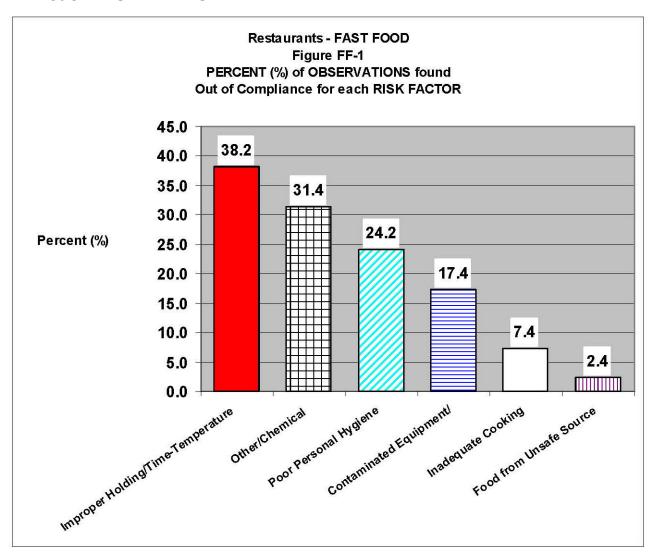
Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)
	Commercially-processed RTE, PHF/TCS Food date marked
Improper Holding/	PHF/TCS Food held hot 140°F or above
Time & Temperature	PHF/TCS Food held cold at 41°F or below
	RTE, PHF/TCS Food date marked after 24 hours
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F
Poor Personal Hygiene	Proper, adequate handwashing
	Handwashing facility, convenient/accessible
	Surfaces/Utensils cleaned/sanitized
Contaminated Equipment/ Protection from Contamination	Raw animal food separated from ready-to-eat foods
Protection from Contamination	Raw animal foods, separated
Other/Chemical	Poisonous or toxic materials properly identified, stored, and used

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A. Percent of observations found Out of Compliance for each RISK FACTOR



FOODBORNE ILLNESS RISK FACTOR	# OUT	Total Obs. (IN & OUT)	
Improper Holding/Time & Temperature	168	440	38.2%
Other/Chemical	33	105	31.4%
Poor Personal Hygiene	122	505	24.2%
Contaminated Equipment/Protection from Contamination	79	455	17.4%
Inadequate Cooking	13	176	7.4%
Food From Unsafe Sources	5	209	2.4%

Discussion for Figure FF-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Chemical contamination, poor personal hygiene, and contaminated equipment/protection from contamination also had notable Out of Compliance percentages. Management systems that were implemented to ensure foods were adequately cooked and from safe sources appeared to be effective during this data collection period.

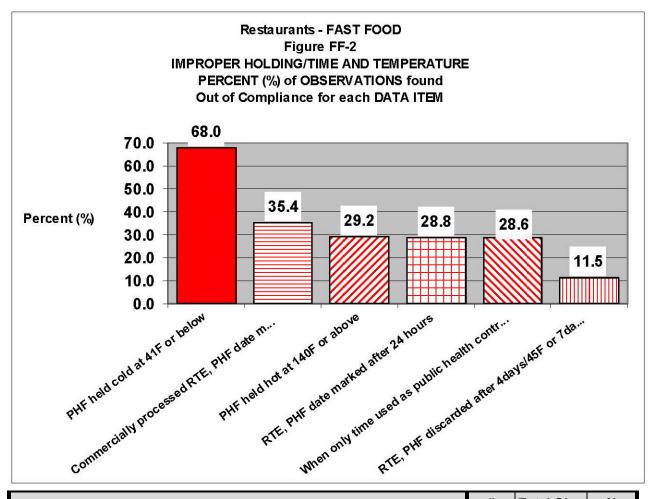
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

For fast food restaurants, the foodborne illness risk factors most in need of attention and their corresponding Out of Compliance percentages are as follows:

- Improper Holding/Time and Temperature (38.2%)
- Other/Chemical (31.4%)
- Poor Personal Hygiene (24.2%)
- Contaminated Equipment/Protection from Contamination (17.4%)

Figures FF-2 through FF-4 provide a breakdown of three of these risk factors into data items that represent specific food preparation procedures and employee behaviors in need of attention. These figures provide insight into the relative strengths and weaknesses of the food safety management systems in place in fast food restaurants to control each of the risk factors during the 2008 data collection.

The Out of Compliance percentage noted for the other/chemical risk factor is primarily attributed to one data item, depicted in Table 16. A summary of the results of the Out of Compliance observations for the identification, storage, and use of chemicals/toxic materials data item is presented as part of the discussion.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	PHF/TCS Food held cold at 41°F or below	70	103	68.0%
	Commercially-processed, RTE, PHF/TCS Food date marked	23	65	35.4%
	PHF/TCS Food held hot at 140°F or above	26	89	29.2%
	RTE, PHF/TCS Food date marked after 24 hours	19	66	28.8%
	When time only is used as a public health control, food is cooked and served within 4 hours	6	21	28.6%
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F	7	61	11.5%
*	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours*	11	18	*
*	PHF/TCS Food (prepared from ingredients at ambient temp.) is cooled to 41°F or below within 4 hours*	5	11	*
*	Roasts are held at a temperature of 130°F or above*	1	5	*
*	Foods received at temperatures according to Law are cooled to 41°F within 4 hours*	0	1	*

^{*} These four Improper Holding/Time & Temperature Data Items do not appear in Figure FF-2 due to a low number of total observations (obs.)

Discussion for Figure FF-2

For the improper holding/time and temperature risk factor, there is a need to review food safety systems related to the following:

- Maintaining cold holding temperatures for PHF/TCS Food (68.0%)
- Date marking of open containers of commercially-processed, ready-to-eat PHF/TCS Food (35.4%)
- Maintaining hot holding temperatures for PHF/TCS Food (29.2%)
- Date marking ready-to eat, PHF/TCS Food made on site (28.8%)
- Time alone used as a public health control (28.6%)

Cold and Hot Holding of PHF/TCS Food

Holding PHF/TCS Food at the proper hot or cold temperatures is critical to preventing the growth of bacteria. Equipment, processes, and monitoring procedures related to maintaining temperature control for PHF/TCS Food need to be assessed, and corrective action should be taken if necessary. Control of cold holding temperatures and date marking provide interlocking protection by slowing the growth of *Listeria monocytogenes* and establishing a time limit for discarding food before the organism can multiply to dangerous levels.

Date Marking

Date marking of refrigerated ready-to-eat, PHF/TCS Food is an important food safety management system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF/TCS Food that has remained in cold storage beyond the parameters described in the *Food Code* prevents foods with a harmful level of *Listeria monocytogenes* from being served.

When cooling, cold holding, and date marking are viewed in the context of a total food safety management system, the potential for bacterial growth increases with each uncontrolled process step. It is essential that each process step be routinely monitored in a manner that enables the manager to take prompt corrective actions before an unsafe product reaches the consumer.

Time Alone Used as a Public Health Control

Per the 1997 FDA Food Code, PHF/TCS Food may be held without temperature control for short time periods (not exceeding four hours) because there will be no significant growth of microorganisms or toxin production possible in that limited time. However, the process requires careful monitoring and documentation to keep track of elapsed time and identification of food products. Written procedures must maintained and available to the regulatory authority. Without an appropriate system in place, the process can create an unacceptable level of risk. Foodservice managers using time alone as a public health control should regularly review their written procedures and confirm adequate implementation of their system.

Discussion for the Other/Chemical Risk Factor

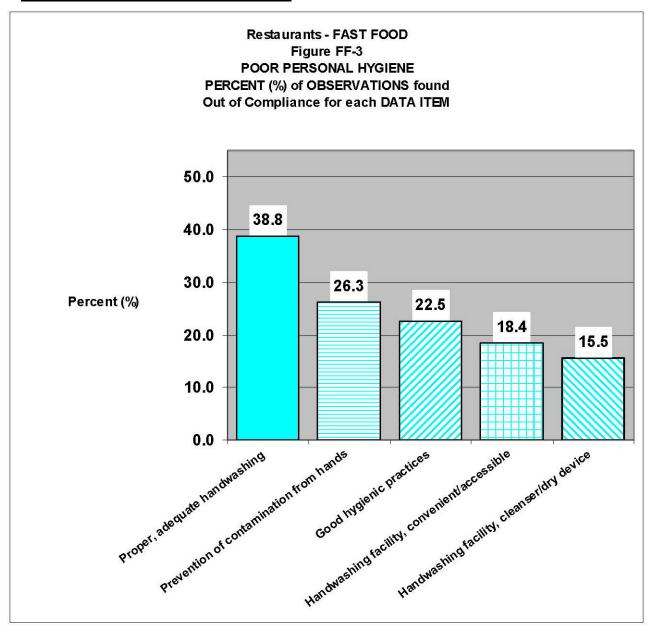
Table 16

Assessment of the Other/Chemical Category – FAST FOOD RESTAURANTS

Poisonous or Toxic Materials are Properly Identified, Stored, and Used

32	103	31.1%

Most of the Out of Compliance observations relating to the other/chemical risk factor are attributed to one data item. The proper identification, storage, and use of cleaners, sanitizers, and other chemicals in fast food restaurants are in need of attention. Food safety procedures related to the identification, storage, and use of cleaners, sanitizers, and other chemicals need to be reviewed and revised, if necessary, to address any gaps in the program that may be contributing to the Out of Compliance observations for this data item.



DATA ITEM		Total Obs. (IN & OUT)	% OUT
Proper, adequate handwashing	38	98	38.8%
Prevention of contamination from hands	26	99	26.3%
Good hygienic practices	23	102	22.5%
Handwashing facility, convenient/accessible	19	103	18.4%
Handwashing facility, cleanser/drying device	16	103	15.5%

Discussion for Figure FF-3

The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include the following:

- Proper, adequate handwashing (38.8%)
- Prevention of contamination from hands (26.3%)
- Good hygienic practices (22.5%)
- Handwashing facility, convenient/accessible (18.4%)
- Handwashing facility, cleanser/drying device (15.5%)

Proper, Adequate Handwashing

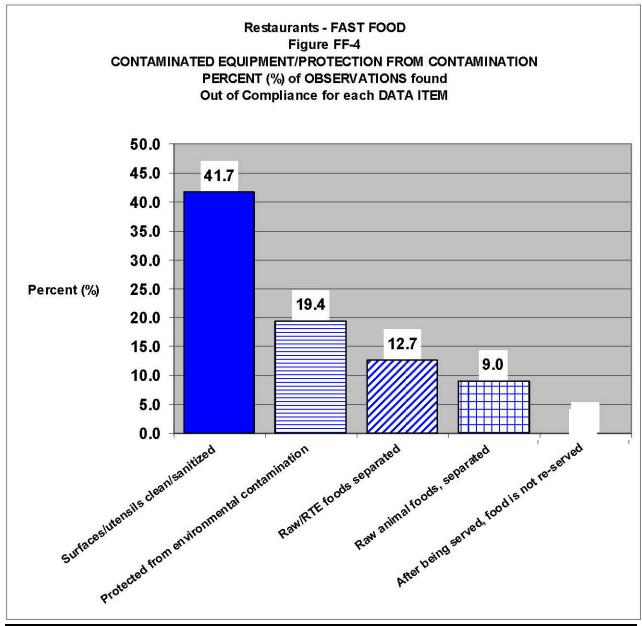
Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom, or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities and/or supplies of hand cleanser/drying devices may contribute to a lack of proper handwashing. Also, the temporary placement of mobile equipment in front of the hand sink and the use of handwashing facilities for other purposes can limit employee access and discourage handwashing. Paragraph 2-103.11(D) of the 1997 Food Code specifically addresses the manager's responsibility to routinely monitor the effectiveness of employee handwashing. Reinforcing the importance of handwashing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of handwashing practices.

Prevention of Contamination From Hands

Handwashing alone may not prevent the transmission of pathogens to foods via hand contact; therefore, preventing bare hand contact with ready-to-eat foods is an essential control measure for limiting the spread of harmful bacteria and viruses from the hands to ready-to-eat food. Reinforcing the importance of preventing bare hand contact with ready-to-eat foods should be supported by a management system that includes proper employee training and monitoring of practices to identify to what extent procedures are being followed.

Good Hygienic Practices

Proper hygienic practices by food employees minimize the possibility of transmitting disease through food. Employee practices such as eating, drinking, and smoking in food preparation areas and working while experiencing persistent coughing and sneezing must be prohibited. Elimination of these practices will help prevent the transfer of microorganisms to foods and food-contact surfaces.



DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	43	103	41.7%
Protected from environmental contamination	20	103	19.4%
Raw/RTE foods, separated	10	79	12.7%
Raw animal foods, separated	6	67	9.0%
After being served, food is not re-served	0	103	0.0%

Discussion for Figure FF-4

The food safety procedures for the contaminated equipment/protection from contamination risk factor that are in most need of attention include the following:

- Cleaning and sanitizing food contact surfaces and utensils (41.7%)
- Protecting from environmental contamination (19.4%)
- Separating raw animal foods from ready-to-eat foods (12.7%)

Cleaning and Sanitizing

Proper cleaning and sanitization of food-contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and clean-in-place equipment such as slicers and mixers are cleaned and sanitized between uses.

The high Out of Compliance percentage for cleaning and sanitizing food-contact surfaces and utensils indicates a weakness in fast food restaurant management systems designed to prevent cross-contamination.

<u>Protection from Environmental Contamination</u>

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, condensate waste, or chemicals. These contaminants may be introduced by other products or equipment stored in close proximity or by persons who are delivering, stocking, or opening packages. Foodservice managers must ensure that standard operating procedures are in place to protect food from environmental contamination from the moment it is received until it is served or sold to the consumer. Except during cooling, stored products should be covered or wrapped to prevent the entry of microbes and other contaminants.

Separation of Raw Animal Foods from Ready-to-Eat Foods

Raw animal foods are a potential source of contamination in any food operation. Storing raw animal foods above or in close proximity to ready-to-eat foods increases the potential for food to become contaminated. To prevent cross-contamination, raw animal foods should also be separated by species based on required minimum cooking temperatures. Required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters may vary with different type of raw animal foods. Storing raw animal foods in organized, designated areas will help prevent cross-contamination of foods.

Preventing cross-contamination between raw animal foods and ready-to-eat foods extends to the food preparation area. Designated separate food preparation areas should be provided for raw and ready-to-eat products. If common preparation areas

must be used, then procedures must be in place to ensure proper cleaning and sanitizing between products.

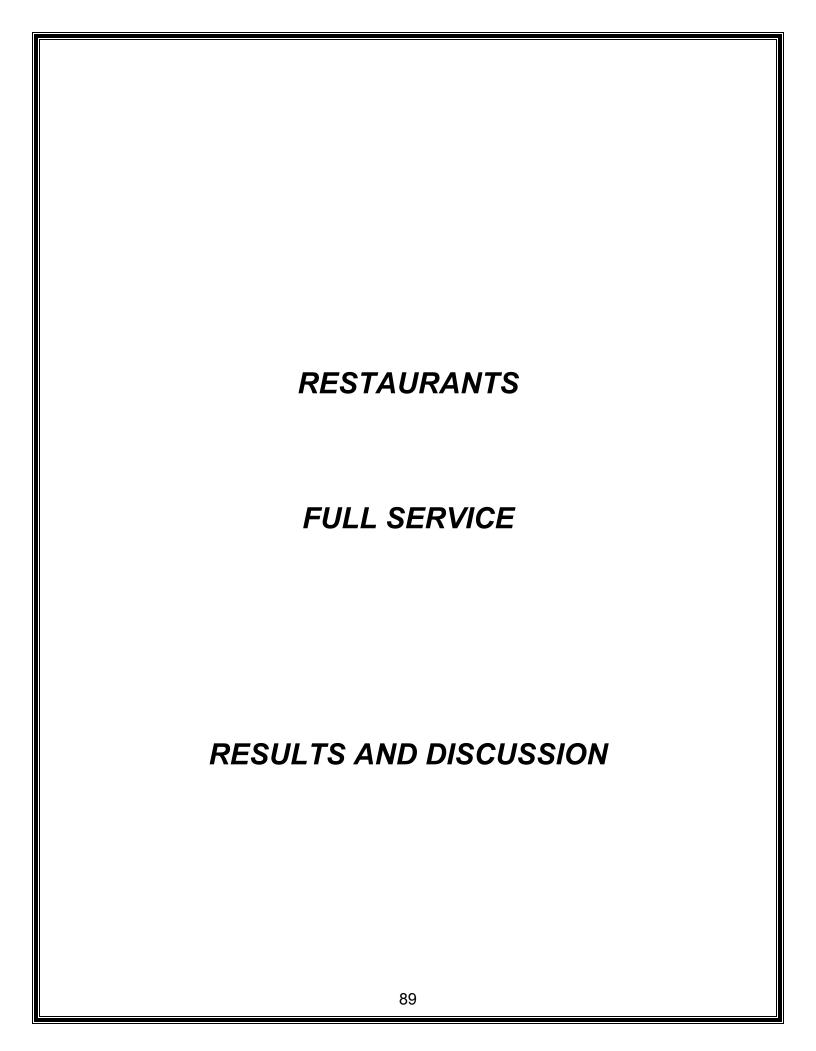
C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

Table 17

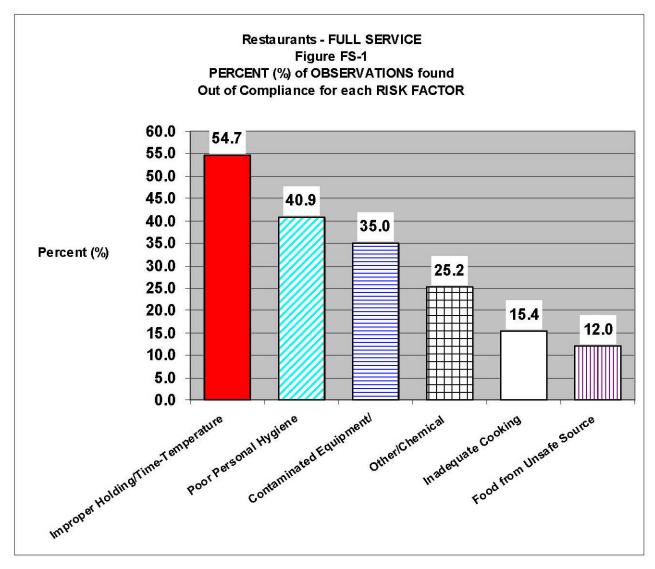
Restaurants - FAST FOOD

Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)
Improper Holding/	PHF/TCS Food held cold at 41°F or below Commercially-processed RTE, PHF/TCS Food date
Time & Temperature	marked PHF/TCS Food held hot at 140°F or above
	RTE, PHF/TCS Food date marked after 24 hours Time alone used as a public health control
Other/Chemical	Poisonous or toxic materials properly identified, store, and used
	Drawar, adaminata handiyyadhina
Poor Personal Hygiene	Proper, adequate handwashing Prevention of contamination from hands
Poor Personal Hygiene	
Poor Personal Hygiene	Prevention of contamination from hands
Poor Personal Hygiene	Prevention of contamination from hands Good hygienic practices
Contaminated Equipment/	Prevention of contamination from hands Good hygienic practices Handwashing facility, convenient/accessible
	Prevention of contamination from hands Good hygienic practices Handwashing facility, convenient/accessible Handwashing facility, cleanser/drying device



A. Percent of observations found Out of Compliance for each RISK FACTOR



FOODBORNE ILLNESS RISK FACTOR	# OUT	Total Obs. (IN & OUT)	% OUT
Improper Holding/Time & Temperature	261	477	54.7%
Poor Personal Hygiene	195	477	40.9%
Contaminated Equipment/ Protection from Contamination	165	471	35.0%
Other/Chemical	26	103	25.2%
Inadequate Cooking	35	227	15.4%
Food From Unsafe Sources	29	242	12.0%

Discussion for Figure FS-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Poor personal hygiene, contaminated equipment/protection from contamination, chemical contamination, inadequate cooking, and food from unsafe sources contain some data items with notable Out of Compliance percentages.

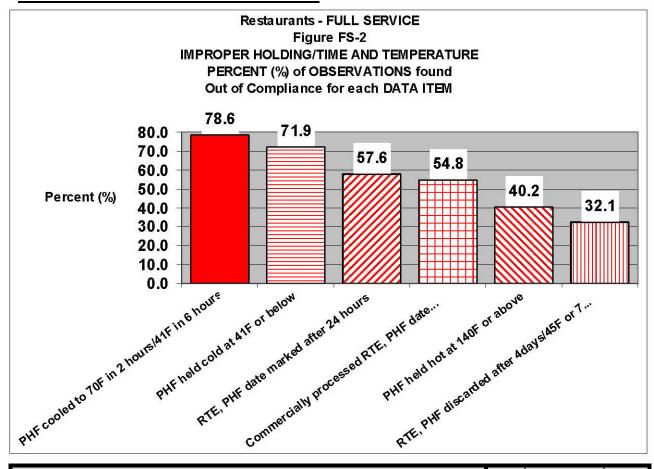
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

For full service restaurants, the foodborne illness risk factors most in need of attention and their Out of Compliance percentages are as follows:

- Improper Holding/Time Temperature (54.7%)
- Poor Personal Hygiene (40.9%)
- Contaminated Equipment/Protection from Contamination (35.0%)
- Other/Chemical (25.2%)
- Inadequate Cooking (15.4%)
- Food from Unsafe Sources (12.0%)

Figures FS-2 through FS-4 provide a breakdown for the first three of these risk factors into data items that represent specific food preparation procedures and employee behaviors in need of attention. These figures provide insight into the relative strengths and weaknesses of the food safety management systems in place in full service restaurants to control each of the risk factors during the 2008 data collection.

The other/chemical, inadequate cooling, and food from unsafe sources risk factors each had a few data items that are in need of attention, as noted in Tables 18-21. Further information for these data items is presented as part of the discussion.



DATA ITEM		# OUT	Total Obs. (IN & OUT)	% OUT
	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours	33	42	78.6%
	PHF/TCS Food held cold at 41°F or below	69	96	71.9%
	RTE, PHF/TCS Food date marked after 24 hours	53	92	57.6%
	Commercially-processed, RTE, PHF/TCS Food date marked	40	73	54.8%
	PHF/TCS Food held hot at 140°F or above	35	87	40.2%
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F	18	56	32.1%
*	When time only is used as a public health control, food is cooked and served within 4 hours*	5	8	*
*	PHF/TCS Food (prepared from ingredients at ambient temp.) is cooled to 41°F or below within 4 hours*	6	16	*
*	Roasts are held at a temperature of 130°F or above*	2	6	*
*	Foods received at temperatures according to Law are cooled to 41°F within 4 hours*	0	1	*

^{*} These four Improper Holding/Time & Temperature Data Items do not appear in Figure FS-2 due to a low number of total observations (obs.)

Discussion for Figure FS-2

For the improper holding/time and temperature risk factor, there is a need to review food safety systems related to the following:

- Cooling of cooked or reheated PHF/TCS Food (78.6%)
- Maintaining cold holding temperatures for PHF/TCS Food (71.9%)
- Date marking of ready-to eat, PHF/TCS Food made on-site (57.6%)
- Date marking open containers of commercially-processed, ready-to-eat PHF/TCS Food (54.8%)
- Maintaining hot holding temperatures for PHF/TCS Food (40.2%)
- Discarding RTE, PHF/TCS Food after they have exceeded time/temperature storage limits (32.1%)

Cooling of PHF/TCS Food

Safe cooling requires the removal of heat from foods quickly enough to prevent the growth of spore-forming pathogens. Foodservice managers within full service restaurants need to ensure their practices and procedures are capable of rapidly cooling PHF/TCS Food.

The total number of observations for cooling was substantially less than the total number of observations for other data items. The time of day the data was collected and the length of the time available to spend in a facility were significant factors limiting the number of observations of cooling. In some situations, for example, as much as six hours may be required on-site to document compliance with the *Food Code* critical limits for cooling. Nevertheless, observations made of cooked or reheated PHF/TCS Food during cooling showed a high Out of Compliance percentage, and due to the critical nature of the procedure, this process warrants attention.

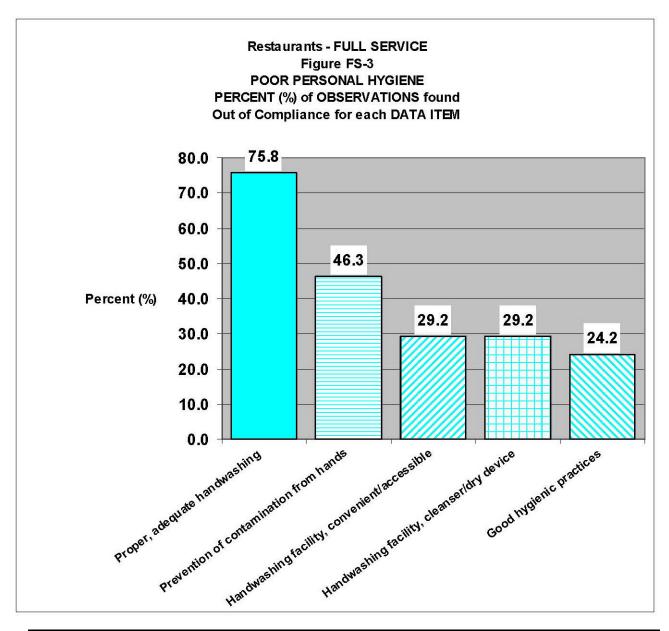
Cold and Hot Holding of PHF/TCS Food

Holding PHF/TCS Food at the proper hot or cold temperatures is critical to preventing the growth of bacteria. Equipment, processes, and monitoring procedures related to maintaining temperature control for PHF/TCS Food need to be assessed, and corrective action should be taken if necessary. Control of cold holding temperatures and date marking provide interlocking protection by slowing the growth of *Listeria monocytogenes* and establishing a time limit for discarding food before the organism can multiply to dangerous levels.

Date Marking

Date marking of refrigerated ready-to-eat, PHF/TCS Food such as deli meats, meat or seafood salads, and soft cheeses is an important food safety management system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF/TCS Food that has remained in cold storage beyond the parameters described in the *Food Code* prevents foods with a harmful level of *Listeria monocytogenes* from being served.

When cooling, cold holding, and date marking are viewed in the context of a total food safety system, the potential for bacterial growth increases with each uncontrolled process step. It is essential that each process step be routinely monitored in a manner that enables the manager to take prompt corrective actions before an unsafe product reaches the consumer.



DATA ITEM		# OUT	Total Obs. (IN & OUT)	% OUT
	Proper, adequate handwashing	72	95	75.8%
	Prevention of contamination from hands	44	95	46.3%
	Handwashing facility, convenient/accessible	28	96	29.2%
	Handwashing facility, cleanser/drying device	28	96	29.2%
	Good hygienic practices	23	95	24.2%

Discussion for Figure FS-3

The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include the following:

- Proper, adequate handwashing (75.8%)
- Prevention of contamination from hands (46.3%)
- Handwashing facility, convenient/accessible (29.2%)
- Handwashing facility, cleanser/drying device (29.2%)
- Good hygienic practices (24.2%)

Proper, Adequate Handwashing/Handwashing Facilities

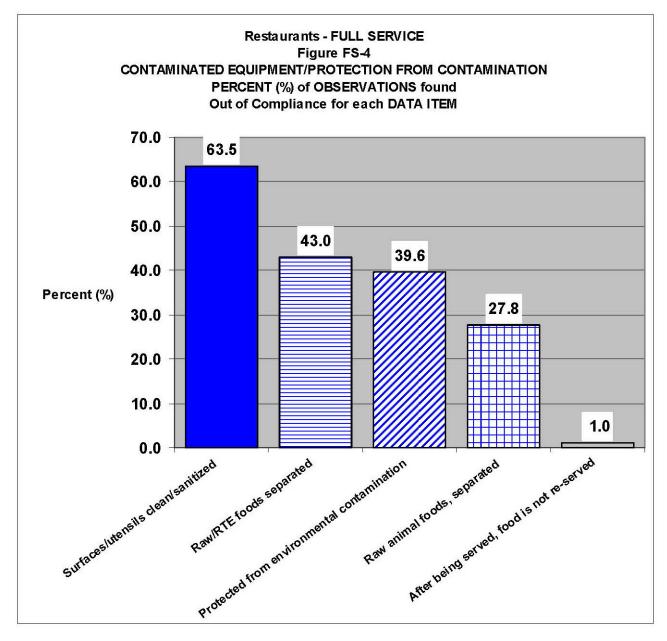
Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom, or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities and/or supplies of hand cleanser/drying devices may contribute to a lack of proper handwashing. Also, the temporary placement of mobile equipment in front of the hand sink and the use of handwashing facilities for other purposes can limit employee access and discourage handwashing. Paragraph 2-103.11(D) of the 1997 Food Code specifically addresses the manager's responsibility to routinely monitor the effectiveness of employee handwashing. Reinforcing the importance of handwashing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of handwashing practices.

Prevention of Contamination From Hands

Handwashing alone may not prevent the transmission of pathogens to foods via hand contact; therefore, preventing bare hand contact with ready-to-eat foods is an essential control measure for limiting the spread of harmful bacteria and viruses from the hands to ready-to-eat food. Reinforcing the importance of preventing bare hand contact with ready-to-eat foods should be supported by a management system that includes proper employee training and monitoring of practices to identify to what extent procedures are being followed.

Good Hygienic Practices

Proper hygienic practices by food employees minimize the possibility of transmitting illness through food. Employee practices such as eating, drinking and smoking in food preparation areas and working while experiencing persistent coughing and sneezing must be prohibited. Elimination of these practices will help prevent the transfer of microorganisms to foods and food-contact surfaces.



DATA ITEM		# OUT	Total Obs. (IN & OUT)	% OUT
	Surfaces/Utensils cleaned/sanitized	61	96	63.5%
	Raw/RTE foods, separated	40	93	43.0%
	Protected from environmental contamination	38	96	39.6%
	Raw animal foods, separated	25	90	27.8%
	After being served, food is not re-served	1	96	1.0%

Discussion for FS-4

The food safety procedures for the contaminated equipment/protection from contamination risk factor that are most in need of attention include the following:

- Cleaning and sanitizing food-contact surfaces and utensils (63.5%)
- Separating raw animal foods from ready-to-eat foods (43.0%)
- Protection from environmental contamination (39.6%)
- Separating raw animal foods (27.8%)

Cleaning and Sanitizing

Proper cleaning and sanitization of food-contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and clean-in-place equipment such as slicers and mixers are cleaned and sanitized between uses.

The high Out of Compliance percentage for cleaning and sanitizing food-contact surfaces and utensils indicates a weakness in full service restaurant management systems designed to prevent cross-contamination.

Separation of Raw Animal Foods from Each Other and from Ready-to-Eat Foods

Raw animal foods are a potential source of contamination in any food operation. Storing raw animal foods above or in close proximity to ready-to-eat foods increases the potential for food to become contaminated. To prevent cross-contamination, raw animal foods should also be separated by species based on required minimum cooking temperatures. Required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters may vary with different types of raw animal foods. Having organized, designated areas for the safe storage of different raw animal products will help prevent cross-contamination of foods.

Preventing cross-contamination between raw animal foods and ready-to-eat foods extends to the food preparation area. Designated, separate food preparation areas should be provided for raw and ready-to-eat products. If common preparation areas must be used, then procedures must be in place to ensure proper cleaning and sanitizing between products.

<u>Protection from Environmental Contamination</u>

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, condensate waste, or chemicals. These contaminants may be introduced by other products or equipment stored in close proximity or by persons who are delivering, stocking, or opening packages.

Foodservice managers must ensure that standard operating procedures are in place to protect food from environmental contamination from the moment it is received until

served or sold to the consumer. Except during cooling, stored products should be covered or wrapped to prevent the entry of microbes and other contaminants.

Discussion for the Other/Chemical Risk Factor

Table 18

Assessment of the Other/Chemical Category FULL SERVICE RESTAURANTS

Poisonous or Toxic Materials are Properly Identified, Stored, and Used

		,	,
26	00		0= 40/
26	96		27.1%

All of the Out of Compliance observations relating to the other/chemical risk factor were attributed to one data item. The proper identification, storage, and use of cleaners, sanitizers, and other chemicals in full service restaurants are in need of attention. Food safety procedures related to the identification, storage, and use of cleaners, sanitizers, and other chemicals need to be reviewed and revised, if necessary, to address any gaps in the program that may be contributing to the Out of Compliance observations made of this data item.

Discussion for the Inadequate Cooking Risk Factor

Cooking and reheating foods to temperatures that destroy pathogens is critical to reducing the risk of foodborne illness. Required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters vary with different types of raw animal foods. The minimum internal product temperature and the time that this temperature must be maintained are dictated by the type of food product being cooked. Proper monitoring and control of cooking operations is central to an effective food safety management system in any establishment.

Reheating of PHF/TCS Food

Table 19

Assessment of the Inadequate Cooking Risk Factor FULL SERVICE RESTAURANTS

PHF/TCS Food Rapidly Reheated to 165°F (74°C) for 15 sec. for Hot Holding

9	22	40.9%

It is important to properly reheat PHF/TCS Food that was initially cooked and cooled on premises and that is to be held hot prior to serving. Reheating these products to 165°F (74°C) for 15 seconds ensures that pathogens that may have contaminated the food after cooking are destroyed and are not given the opportunity to multiply during hot holding. Of the full service restaurants in which reheating of PHF/TCS Food for hot holding was observed, approximately 41% were found to be Out of Compliance.

Cooking of poultry and stuffed food products

Table 20

Assessment of the Inadequate Cooking Risk Factor FULL SERVICE RESTAURANTS

Poultry, Stuffed Fish, Meat, Pasta Cooked to 165°F (74°C) for 15 sec.

_		
5	44	11.4%

Cooking poultry and stuffed food products (fish, meat, pasta, poultry, and ratites) to an internal temperature of 165°F (74°C) for 15 seconds ensures the destruction of bacteria such as *Salmonella* and *Escherichia coli O157:H7* that may be present in the raw product. Of the full service restaurants observed to be cooking these products, approximately 11% were found to be Out of Compliance with this important food safety requirement.

Discussion for the Food from Unsafe Sources Risk Factor

Table 21

Assessment of the Food from Unsafe Sources Risk Factor FULL SERVICE RESTAURANTS

Shellstock Tags Retained for 90 Days

# Observations		
7	14	50.0%

The overall IN Compliance percentage for combined data items that comprise the food from unsafe sources risk factor is high indicating effective management of this area. There is one exception to this general observation – retention of shellstock tags for 90 days.

It is important to note that this data item had only fourteen total observations. Of the observations made, seven were Out of Compliance. Data items with less than twenty total observations have generally not been singled out for discussion in this report. An exception is made here because only a minority of full service restaurants offered shellstock as a menu item. Therefore, one would not expect a large number of observations to be made of this item in full service restaurants.

Shellfish harvested from contaminated water can harbor harmful bacteria and viruses. Effective monitoring of shellfish sources must be continuous and involve all segments of the industry. Retention of shellstock tags for 90 days in chronological order is not a direct contributing factor to the occurrence of foodborne illness. It is, however, an essential management practice that provides a means for conducting tracebacks to the harvest areas if a food-related illness occurs resulting from contaminated shellstock. Restaurant managers serving oysters, clams, and mussels must review their management systems and take corrective action if necessary.

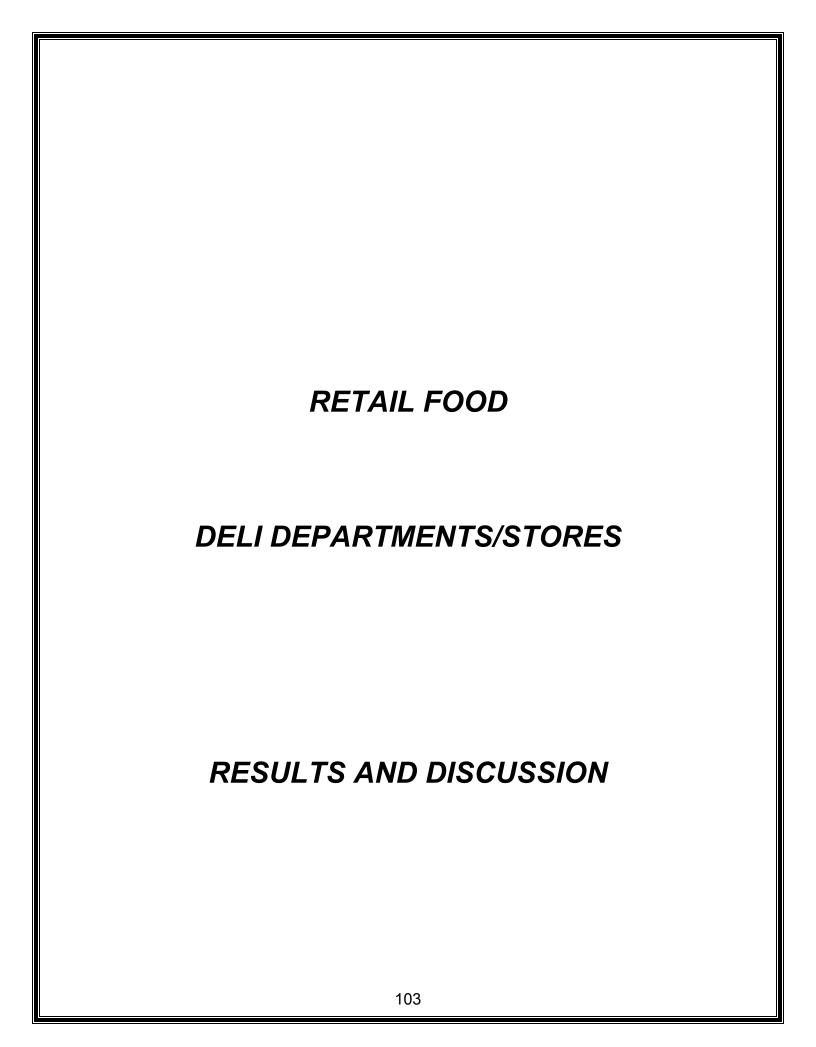
C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

Table 22

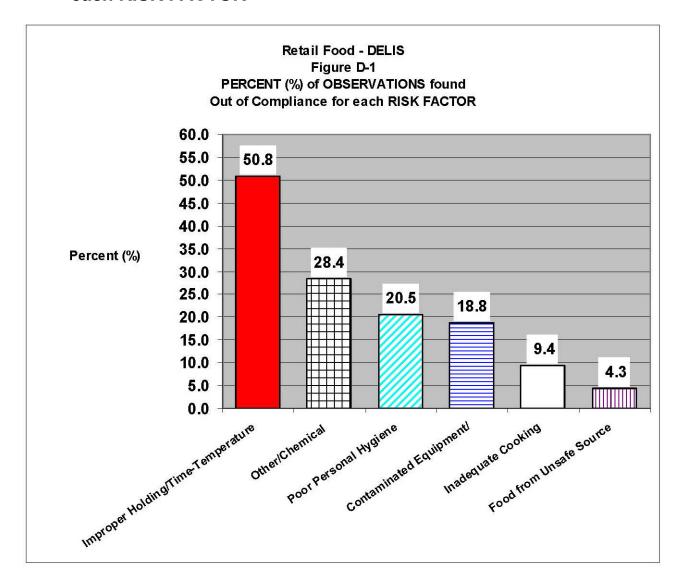
Restaurants – FULL SERVICE

Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)
Improper Holding/ Time & Temperature	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours PHF/TCS Food held cold at 41°F or below RTE, PHF/TCS Food date marked after 24 hours Commercially-processed RTE, PHF/TCS Food date marked PHF/TCS Food held hot at 140°F or above RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F
Poor Personal Hygiene	Proper, adequate handwashing Prevention of contamination from hands Handwashing facility, convenient/accessible Handwashing facility, cleanser/drying device Good hygienic practices
Contaminated Equipment/ Protection from Contamination	Surfaces/Utensils cleaned/sanitized Raw animal food separated from ready-to-eat foods Prevention from environmental contamination Raw animal foods separated from each other
Other/Chemical	Poisonous or toxic materials properly identified, stored, and used
Inadequate Cooking	PHF/TCS Food rapidly reheated to 165°F/ 15 seconds for hot holding Poultry, stuffed fish, meat, pasta cooked to 165°F for 15 seconds
Food from Unsafe Sources	Shellstock tags retained for 90 days



A. Percent of observations found Out of Compliance for each RISK FACTOR



FOODBORNE ILLNESS RISK FACTOR		Total Obs. (IN & OUT)	% OUT
Improper Holding/Time & Temperature	249	490	50.8%
Other/Chemical	29	102	28.4%
Poor Personal Hygiene	100	488	20.5%
Contaminated Equipment/ Protection from Contamination	87	464	18.8%
Inadequate Cooking	12	127	9.4%
Food from Unsafe Sources	9	210	4.3%

Discussion for Figure D-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Chemical contamination, poor personal hygiene, and contaminated equipment/protection from contamination also had notable Out of Compliance percentages. Management systems that were implemented to ensure foods were adequately cooked and from safe sources appeared to be effective during this data collection period.

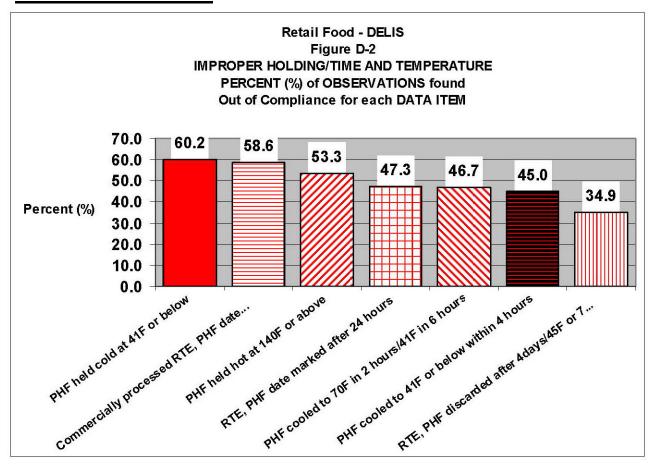
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

For delis, the foodborne illness risk factors most in need of attention with their corresponding Out of Compliance percentages are as follows:

- Improper Holding/Time and Temperature (50.8%)
- Other/Chemical (28.4%)
- Poor Personal Hygiene (20.5%)
- Contaminated Equipment/Protection from Contamination (18.8%)

Figures D-2 through D-4 provide a breakdown of three of these risk factors into data items that represent specific food preparation procedures and employee behaviors in need of attention. These figures provide insight into the relative strengths and weaknesses of the food safety management systems in place in delis to control each of the risk factors during the 2008 data collection.

The other/chemical risk factor had one data item that warrants attention. A summary of the results of the Out of Compliance observations for the identification, storage, and use of chemicals/toxics data item is presented as part of the discussion.



	DATA ITEM		Total Obs. (IN & OUT)	% OUT
	PHF/TCS Food held cold at 41°F or below	59	98	60.2%
	Commercially-processed, RTE, PHF/TCS Food date marked	51	87	58.6%
	PHF/TCS Food held hot at 140°F or above	49	92	53.3%
	RTE, PHF/TCS Food date marked after 24 hours	43	91	47.3%
	PHF/TCS Food cooled to 70°F in 2 hours/41 °F in total of 6 hours	14	30	46.7%
	PHF/TCS Food (prepared from ingredients at ambient temp.) is cooled to 41°F or below within 4 hours	9	20	45.0%
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F	22	63	34.9%
*	When time only is used as a public health control, food is cooked and served within 4 hours*	2	4	*
*	Roasts are held at a temperature of 130°F or above*	0	2	*
*	Foods received at temperatures according to Law are cooled to 41°F within 4 hours*	0	3	*

These three Improper Holding/Time & Temperature Data Items do not appear in Figure D-2 due to a low number of total observations (obs.)

Discussion for Figure D-2

For the improper holding/time and temperature risk factor, there is a need to review and take corrective action for food safety management systems related to the following:

- Maintaining cold holding temperatures for PHF/TCS Food (60.2%)
- Date marking of open containers of commercially-processed, ready-to-eat, PHF/TCS Food (58.6%)
- Maintaining hot holding temperatures for PHF/TCS Food (53.3%)
- Date marking ready-to eat, PHF/TCS Food made on-site (47.3%)
- Cooling of cooked or reheated PHF/TCS Food (46.7%)
- Cooling PHF/TCS Food products prepared from ingredients at ambient air temperature (45.0%)
- Discarding RTE, PHF/TCS Food after they have exceeded time/temperature storage limits (34.9%)

Cold and Hot Holding of PHF/TCS Food

Holding PHF/TCS Food at the proper hot or cold temperatures is critical to preventing the growth of bacteria. Equipment, processes, and monitoring procedures related to maintaining temperature control for PHF/TCS Food need to be assessed, and corrective action should be taken if necessary. Control of cold holding temperatures and date marking provide interlocking protection by slowing the growth of *Listeria monocytogenes* and establishing a time limit for discarding food before the organism can multiply to dangerous levels.

Date Marking

Date marking of refrigerated ready-to-eat, PHF/TCS Food such as deli meats, meat salads, and soft cheeses is an important food safety management system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF/TCS Food that has remained in cold storage beyond the parameters described in the *Food Code* prevents foods with a harmful level of *Listeria monocytogenes* from being served.

Cooling of PHF/TCS Food

Safe cooling requires the removal of heat from foods quickly enough to prevent the growth of spore-forming pathogens. Deli foodservice directors and managers need to ensure their practices and procedures are capable of rapidly cooling PHF/TCS Food. The total number of observations for cooling was substantially less than the total number of observations for other data items. The time of day the data was collected and the length of the time available to spend in a facility were significant factors limiting the number of observations of cooling. In some situations, for example, as much as six hours may be required on site to document compliance with the *Food Code* critical limits for cooling. Nevertheless, taking the limited number of observations into account, the

high Out of Compliance percentage for cooling foods that have been cooked or reheated seem to warrant more focused attention on ensuring control of this food safety procedure.

When cooling, cold holding, and date marking are viewed in the context of a total food safety management system, the potential for bacterial growth increases with each uncontrolled process step. It is essential that each process step be routinely monitored in a manner that enables the manager to take prompt corrective actions before an unsafe product reaches the consumer.

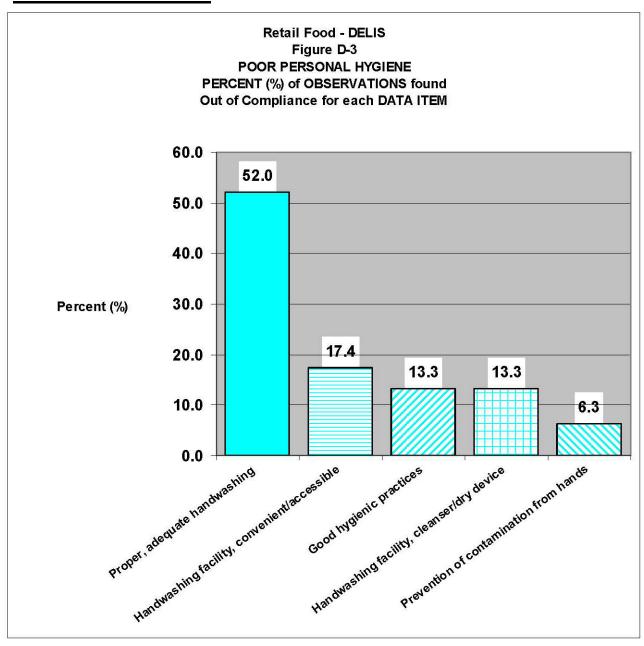
Discussion for the Other/Chemical Risk Factor

Table 23
Assessment of the Other/Chemical Category - DELIS

Poisonous or Toxic Materials are Properly Identified, Stored, and Used

26 98	26.5%

All but three of the Out of Compliance observations relating to the other/chemical risk factor were attributed to one data item. The proper identification, storage, and use of cleaners, sanitizers, and other chemicals in delis are in need of attention. Food safety procedures related to the identification, storage, and use of cleaners, sanitizers, and other chemicals need to be reviewed and revised, if necessary, to address any gaps in the program that may be contributing to the Out of Compliance observations made of this data item



DATA ITEM		Total Obs. (IN & OUT)	% OUT
Proper, adequate handwashing	51	98	52.0%
Handwashing facility, convenient/accessible	17	98	17.4%
Good hygienic practices	13	98	13.3%
Handwashing facility, cleanser/drying device	13	98	13.3%
Prevention of contamination from hands	6	96	6.3%

Discussion for Figure D-3

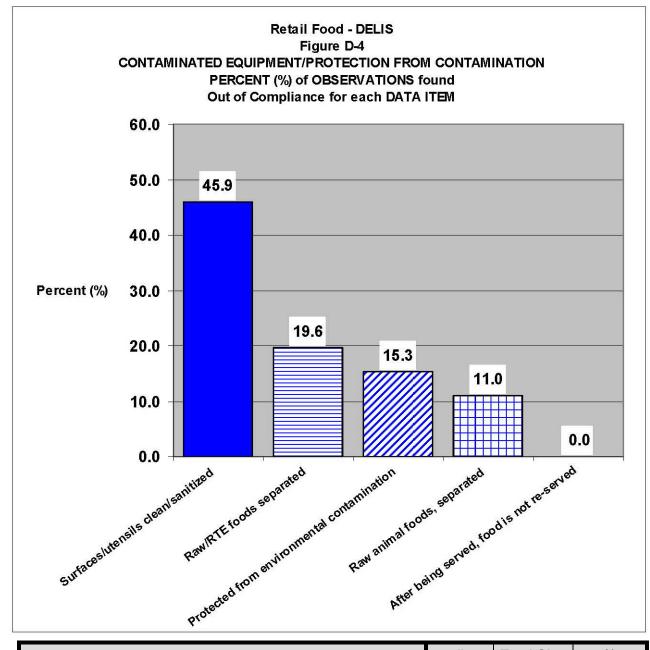
The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include the following:

- Proper, adequate hand washing (52.0%)
- Hand washing facility, convenient/accessible (17.4%)
- Good hygienic practices (13.3%)
- Hand washing facility, cleanser/drying device (13.3%)

Proper, Adequate Handwashing/Handwashing Facilities

Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom, or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities and/or supplies of hand cleanser/drying devices may contribute to a lack of proper handwashing. Also, the temporary placement of mobile equipment in front of the hand sink and the use of handwashing facilities for other purposes can limit employee access and discourage handwashing. Paragraph 2-103.11(D) of the 1997 Food Code specifically addresses the manager's responsibility to routinely monitor the effectiveness of employee handwashing. Reinforcing the importance of handwashing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of handwashing practices.

While handwashing continues to be a primary concern, the results from the 2008 study show a relatively high IN Compliance percentage (93.7%) for preventing direct hand contamination of food in delis. The retail food managers in delis appear to be making a concerted effort to eliminate bare hand contact with ready-to-eat foods.



DATA ITEM		Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	45	98	45.9%
Raw/RTE foods separated	19	97	19.6%
Protected from environmental contamination	15	98	15.3%
Raw animal foods, separated	8	73	11.0%
After being served, food is not re-served	0	98	0.0%

Discussion for Figure D-4

The food safety procedures for the contaminated equipment/protection from contamination risk factor that are most in need of attention include as follows:

- Cleaning and sanitizing food-contact surfaces and utensils (45.9%)
- Separating raw animal foods from ready-to-eat foods (19.6%)
- Protected from environmental contamination (15.3%)

Cleaning and Sanitizing

Proper cleaning and sanitization of food-contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and clean-in-place equipment such as slicers and mixers are cleaned and sanitized between uses.

The high Out of Compliance percentage for cleaning and sanitizing food-contact surfaces and utensils indicates a weakness in deli food safety management systems designed to prevent cross-contamination.

Separation of Raw Animal Foods from Ready-to-Eat Foods

Raw animal foods are a potential source of contamination in any food operation. Storing raw animal foods above or in close proximity to ready-to-eat foods increases the potential for food to become contaminated. To prevent cross-contamination, raw animal foods should also be separated by species based on required minimum cooking temperatures. Required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters may vary with different types of raw animal foods. Having organized, designated areas for the safe storage of different raw animal products will help prevent cross-contamination of foods.

Preventing cross-contamination between raw animal foods and ready-to-eat foods extends to the food preparation area. Designated, separate food preparation areas should be provided for raw and ready-to-eat products. If common preparation areas must be used, then procedures must be in place to ensure proper cleaning and sanitizing between products.

<u>Protection from Environmental Contamination</u>

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, condensate waste, or chemicals. These contaminants may be introduced by other products or equipment stored in close proximity or by persons who are delivering, stocking, or opening packages. Foodservice managers must ensure that standard operating procedures are in place to protect food from environmental contamination from the moment it is received until served or sold to the consumer. Except during cooling, stored products should be covered or wrapped to prevent the entry of microbes and other contaminants.

C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

Table 24

Retail Food Store - DELIS

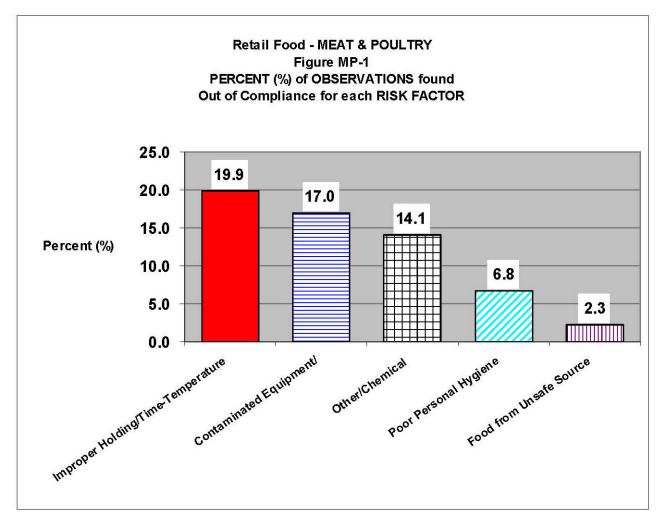
Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS In need of Priority Attention (From Section B)
	PHF/TCS Food held cold at 41°F or below
	Commercially-processed, RTE, PHF/TCS Food date marked
Improper Holding/ Time & Temperature	PHF/TCS Food held hot at 140°F or above
	RTE, PHF/TCS Food date marked after 24 hours
	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours
	PHF/TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F within 4 hours
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F
Other/Chemical	Poisonous or toxic materials properly identified, stored, and used
	Proper, adequate handwashing
Poor Personal Hygiene	Handwashing facility, convenient/accessible
1 ooi i ersonal riygiene	Good hygienic practices
	Handwashing facility, cleanser/drying device
Contaminated Equipment/	Surfaces/Utensils cleaned/sanitized
Protection from Contamination	Raw animal food separated from ready-to-eat foods
	Prevention from contamination

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RETAIL FOOD
MEAT & POULTRY DEPARTMENTS/MARKETS
RESULTS AND DISCUSSION
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A. Percent of observations found Out of Compliance for each RISK FACTOR



	FOODBORNE ILLNESS RISK FACTOR		Total Obs. (IN & OUT)	% OUT
	Improper Holding/Time & Temperature	31	156	19.9%
	Contaminated Equipment/ Protection from Contamination	80	470	17.0%
	Other/Chemical	14	99	14.1%
	Poor Personal Hygiene	29	429	6.8%
	Food from Unsafe Sources	5	220	2.3%
*	Inadequate Cooking*	0	1	*

^{*} Data for the Inadequate Cook Risk Factor is not reflected in the Figure MP-1 due to a low number of observations (Obs.)

Discussion for Figure MP-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Contaminated equipment/protection from contamination, chemical contamination, and poor personal hygiene contained one or more data items with notable Out of Compliance percentages. Management systems that were implemented to ensure foods were adequately cooked and from safe sources appeared to be effective during this data collection period.

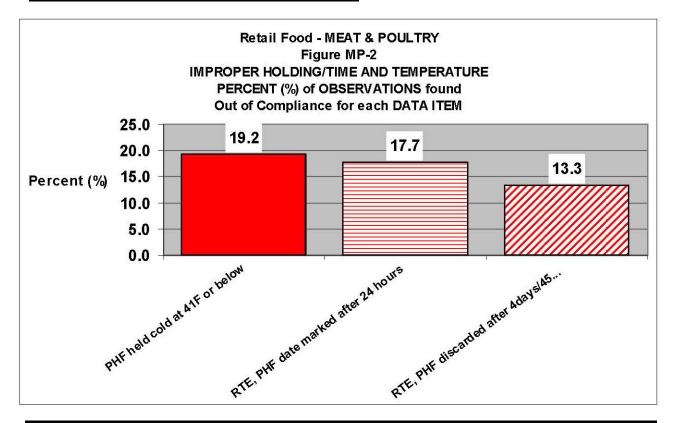
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

For meat and poultry departments, the foodborne illness risk factors most in need of attention and their corresponding Out of Compliance percentages are as follows:

- Improper Holding/Time Temperature (19.9%)
- Contaminated Equipment/Protection from Contamination (17.0%)
- Other/Chemical (14.1%)

Figures MP-2 through MP-4 provide a breakdown for two of these risk factors into data items that represent specific food preparation procedures and employee behaviors in need of attention. These figures provide insight into the relative strengths and weaknesses of the food safety management systems in place in meat and poultry departments to control each of the risk factors during the 2008 data collection.

The other/chemical and poor personal hygiene risk factors each had one data item of interest. A summary of the results of the Out of Compliance observations for the identification, storage, and use of chemicals/toxic materials data item will be presented as part of the chemical contamination discussion. The proper, adequate handwashing data item will be the focus for the discussion of the poor personal hygiene risk factor.



	DATA ITEM		Total Obs. (IN & OUT)	% OUT
	PHF/TCS Food held cold at 41°F or below	19	99	19.2%
**	RTE, PHF/TCS Food date marked after 24 hours**	3	17	17.7%
**	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F**	2	15	13.3%
*	PHF/TCS Food (prepared from ingredients at ambient temp.) is cooled to 41°F or below within 4 hours*	1	12	*
*	PHF/TCS Food held hot at 140°F or above*	2	2	*
*	Commercially-processed, RTE, PHF/TCS Food date marked*	4	9	*
*	Foods received at temperatures according to Law are cooled to 41°F within 4 hours*	0	2	*
*	PHF/TCS Food cooled to 70°F in 2 hours/41°F in total of 6 hours*	0	0	*
*	Roasts are held at a temperature of 130°F or above*	0	0	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0	0	*

^{*} These seven remaining Improper Holding/Time & Temperature Data Items do not appear in Figure MP-2 due to a low number of total observations (obs.)

^{**}These two data items are included in Figure MP-2 even though each has 20 or less total observations. Though there are only a few observations for each data item, they are still of interest due to their relationship to each other – collectively they all pertain to date marking procedures.

Discussion for Figure MP-2

For the improper holding/time and temperature risk factor, there is a need to review food safety management systems related to the following:

- Maintaining cold holding temperatures for PHF/TCS Food (19.2%)
- Date Marking ready-to eat, PHF/TCS Food made on-site (17.7%)
- Discarding RTE, PHF/TCS Food after they have exceeded time/temperature storage limits (13.3%)

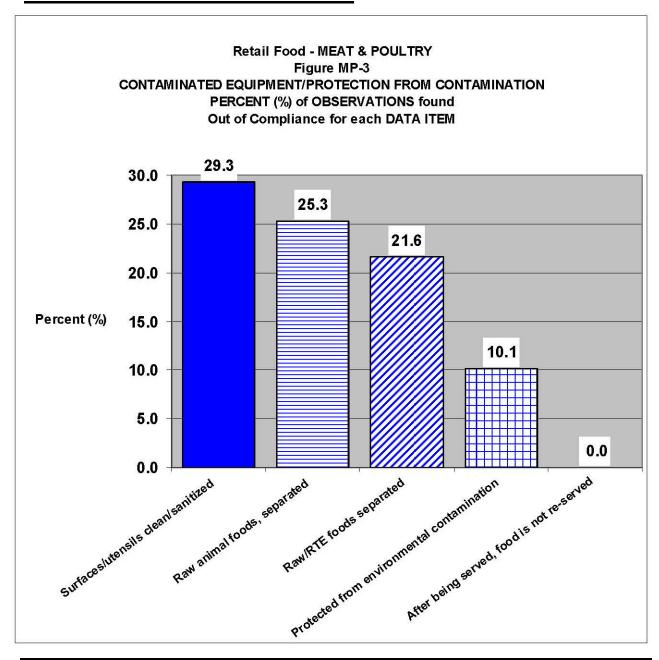
Cold Holding of PHF/TCS Food

Holding PHF/TCS Food at the proper cold temperatures is critical to preventing the growth of bacteria. Equipment, processes, and monitoring procedures related to maintaining temperature control for PHF/TCS Food need to be assessed, and corrective actions should be taken if necessary. Control of cold holding temperatures and date marking provide interlocking protection by slowing the growth of *Listeria monocytogenes* and establishing a time limit for discarding food before the organism can multiply to dangerous levels.

Date Marking

Date marking of refrigerated, ready-to-eat PHF/TCS Food such as salads containing various meats that may be prepared or sold is an important food safety management system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF/TCS Food that has remained in cold storage beyond the parameters described in the *Food Code* prevents foods with a harmful level of *Listeria monocytogenes* from being served.

When cold holding and date marking are viewed in the context of a total food safety management system, the potential for bacterial growth increases with each uncontrolled process step. It is essential that each process step be routinely monitored in a manner that enables the manager to take prompt corrective actions before an unsafe product reaches the consumer.



DATA ITEM		Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	29	99	29.3%
Raw animal foods, separated	25	99	25.3%
Raw/RTE foods, separated	16	74	21.6%
Protected from environmental contamination	10	99	10.1%
After being served, food is not re-served	0	99	0.0%

Discussion for Figure MP-3

The food safety procedures for the contaminated equipment/protection from contamination risk factor that are most in need of attention include the following:

- Cleaning and sanitizing food-contact surfaces and utensils (29.3%)
- Separating raw animal foods from each other (25.3%)
- Separating raw animal foods from ready-to-eat foods (21.6%)

Cleaning and Sanitizing

Proper cleaning and sanitization of food-contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and clean-in-place equipment such as slicers and mixers are cleaned and sanitized between uses.

The high Out of Compliance percentage for cleaning and sanitizing food-contact surfaces and utensils indicates a weakness in meat and poultry department management systems designed to prevent cross-contamination.

Separation of Raw Animal Foods from each other and from Ready-to-Eat Foods

Raw animal foods are a potential source of contamination in any food operation. Storing raw animal foods above or in close proximity to ready-to-eat foods increases the potential for food to become contaminated. To prevent cross-contamination, raw animal foods should also be separated by species based on required minimum cooking temperatures. Required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters may vary with different types of raw animal foods. Having organized, designated areas for different raw animal products and better use of containers, trays, and dividers will help prevent cross-contamination of foods.

Preventing cross-contamination between raw animal foods and ready-to-eat foods extends to the food preparation area. Designated, separate food preparation areas should be provided for raw and ready-to-eat products. If common preparation areas must be used, then procedures must be in place to ensure proper cleaning and sanitizing between products.

Discussion for the Other/Chemical Risk Factor

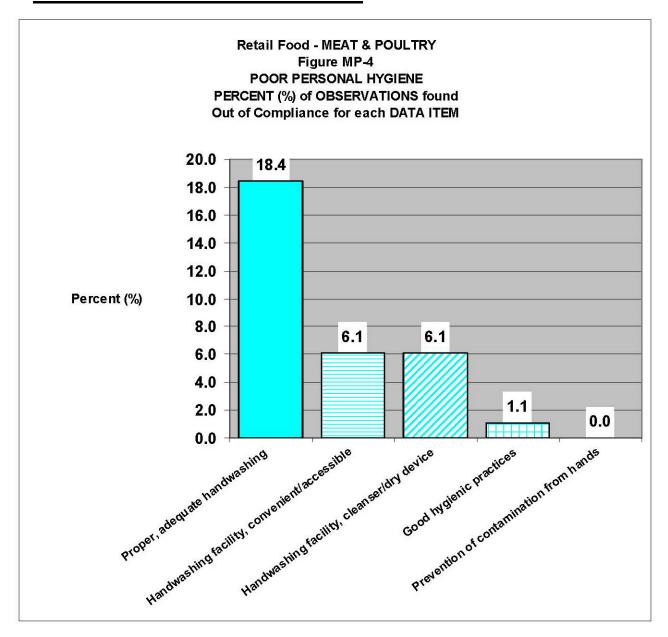
Table 25

Assessment of the Other/Chemical Category – MEAT AND POULTRY

Poisonous or Toxic Materials are Properly Identified, Stored, and Used

		·
14	99	14.1%

All of the Out of Compliance observations relating to the other/chemical risk factor are attributed to one data item. The proper identification, storage, and use of cleaners, sanitizers, and other chemicals in meat and poultry departments are in need of attention. Food safety procedures related to the identification, storage, and use of cleaners, sanitizers and other chemicals need to be reviewed and revised, if necessary, to address any gaps in the program that may be contributing to the Out of Compliance observations of this data item.



DATA ITEM		Total Obs. (IN & OUT)	% OUT
Proper, adequate handwashing	16	87	18.4%
Handwashing facility, convenient/accessible	6	99	6.1%
Handwashing facility, cleanser/drying device	6	99	6.1%
Good hygienic practices	1	94	1.1%
Prevention of contamination from hands	0	50	0.0%

Discussion for Figure MP-4

The food safety procedure for the poor personal hygiene risk factor that is most in need of attention is:

Proper, adequate handwashing (18.4%)

Proper, Adequate Handwashing

Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom, or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities and/or supplies of hand cleanser/drying devices may contribute to a lack of proper handwashing. Also, the temporary placement of mobile equipment in front of the hand sink and the use of handwashing facilities for other purposes can limit employee access and discourage handwashing. Paragraph 2-103.11(D) of the 1997 Food Code specifically addresses the manager's responsibility to routinely monitor the effectiveness of employee handwashing. Reinforcing the importance of handwashing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of handwashing practices.

C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

Table 26

Retail Food Store - MEAT AND POULTRY

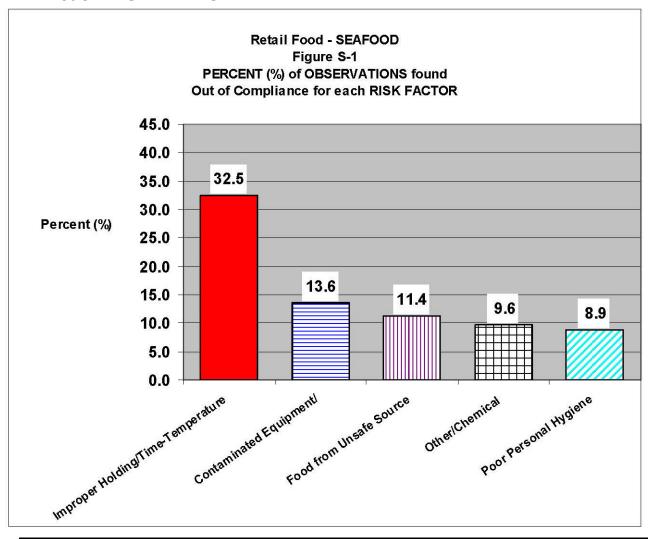
Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)
Improper Holding/ Time & Temperature	PHF/TCS Food held cold at 41°F or below
	RTE, PHF/TCS Food date marked after 24 hours
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F
	Surfaces/Utensils cleaned/sanitized
Contaminated Equipment/ Protection from Contamination	Raw animal foods separated from each other
Protection from Contamination	Raw animal food separated from ready-to-eat foods
Other/Chemical	Poisonous or toxic materials properly identified, stored, and used
Poor Personal Hygiene	Proper, adequate handwashing

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A. Percent of observations found Out of Compliance for each RISK FACTOR



		# OUT	Total Obs. (IN & OUT)	% OUT
	Improper Holding/Time & Temperature	63	194	32.5%
	Contaminated Equipment/Protection from Contamination	52	381	13.6%
	Food from Unsafe Sources	34	299	11.4%
	Other/Chemical	8	83	9.6%
	Poor Personal Hygiene	34	382	8.9%
*	Inadequate Cooking*	0	3	*

^{*} Data for the Inadequate Cook Risk Factor is not reflected in the Figure S-1 due to a low number of observations (obs.)

Discussion for Figure S-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Contaminated equipment/protection from contamination, food from unsafe sources, and poor personal hygiene each had data items that warrant attention.

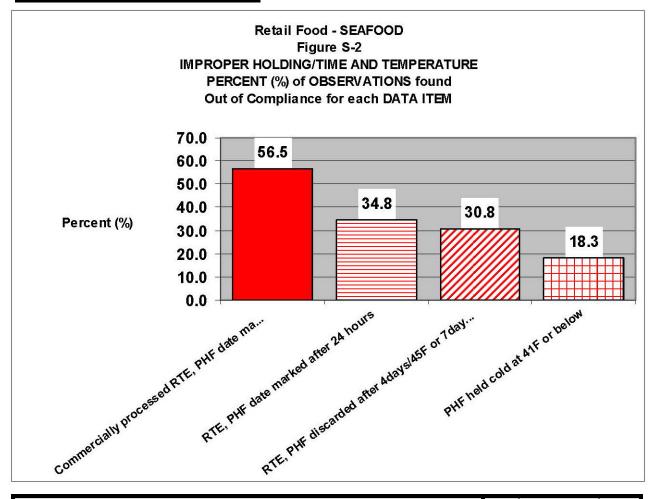
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

For seafood departments, the foodborne illness risk factors most in need of attention and their corresponding Out of Compliance percentages are as follows:

- Improper Holding/Time and Temperature (32.5%)
- Contaminated Equipment/Protection from Contamination (13.6%)
- Food from Unsafe Sources (11.4%)

Figures S-2 through S-4 provide a breakdown for two of these risk factors into data items that represent specific food preparation procedures and employee behaviors in need of attention. These figures provide insight into the relative strengths and weaknesses of the food safety management systems in place in seafood operations to control each of the risk factors during the 2008 data collection.

The food from unsafe sources and poor personal hygiene risk factors each had one data item of interest. A summary of the results of the Out of Compliance observations for the retention of shellfish tags will be presented as part of the discussion. The proper, adequate handwashing data item will be the focus for the discussion of the poor personal hygiene risk factor.



DATA ITEM		# OUT	Total Obs. (IN & OUT)	% OUT
	Commercially-processed, RTE, PHF/TCS Food date marked	26	46	56.5%
	RTE, PHF/TCS Food date marked after 24 hours	8	23	34.8%
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F	8	26	30.8%
	PHF/TCS Food held cold at 41°F or below	15	82	18.3%
*	PHF/TCS Food held hot at 140°F or above*	1	1	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	1	1	*
*	PHF/TCS Food (prepared from ingredients at ambient temp.) is cooled to 41°F or below within 4 hours*	4	9	*
*	PHF/TCS Food cooled to 70°F on 2 hours/41°F in total of 6 hours*	0	3	*
*	Foods received at temperatures according to Law are cooled to 41°F within 4 hours*	0	3	*
*	Roasts are held at a temperature of 130°F or above*	0	0	*

^{*} These six Improper Holding/Time & Temperature Data Items do not appear in Figure S-2 due to a low number of total observations (obs.)

Discussion for Figure S-2

For the improper holding/time and temperature risk factor, there is a need to review food safety systems related to the following:

- Date marking of open containers of commercially-processed, ready-to-eat, PHF/TCS Food (56.5%)
- Date marking ready-to eat, PHF/TCS Food made on-site (34.8%)
- Discarding RTE, PHF/TCS Food after they have exceeded time/temperature storage limits (30.8%)
- Maintaining cold holding temperatures for PHF/TCS Food (18.3%)

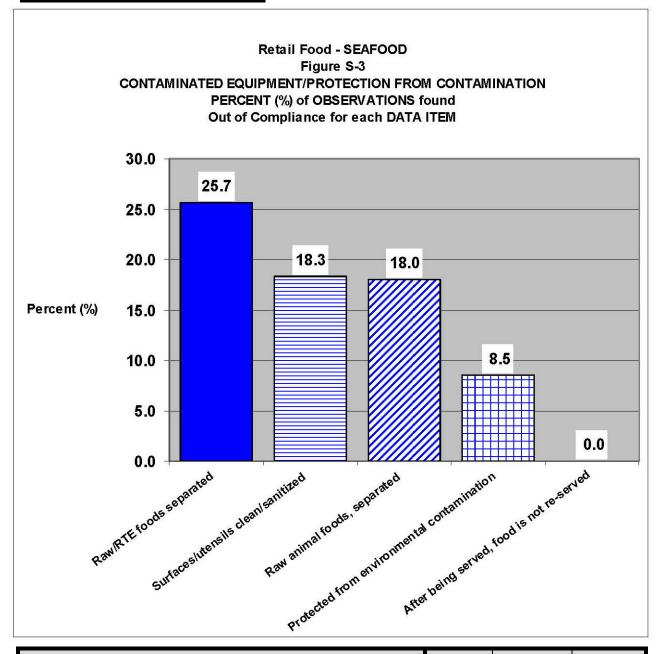
Date Marking

Date marking of refrigerated ready-to-eat, PHF/TCS Food such as seafood salads that may be prepared or sold is an important food safety management system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF/TCS Food that have remained in cold storage beyond the parameters described in the *Food Code* prevents foods with a harmful level of *Listeria monocytogenes* from being served.

Cold Holding of PHF/TCS Food

Holding PHF/TCS Food at the proper cold temperatures is critical to preventing the growth of bacteria. Equipment, processes, and monitoring procedures related to maintaining temperature control for PHF/TCS Food need to be assessed and corrective actions taken if necessary. Control of cold holding temperatures and date marking provide interlocking protection by slowing the growth of *Listeria monocytogenes* and establishing a time limit for discarding food before the organism can multiply to dangerous levels.

When cold holding and date marking are viewed in the context of a total food safety management system, the potential for bacterial growth increases with each uncontrolled process step. It is essential that each process step be routinely monitored in a manner that enables the manager to take prompt corrective action before an unsafe product reaches the consumer.



DATA ITEM		# OUT	Total Obs. (IN & OUT)	% OUT
	Raw/RTE foods, separated	19	74	25.7%
	Surfaces/Utensils cleaned/sanitized	15	82	18.3%
	Raw animal foods, separated	11	61	18.0%
	Protected from environmental contamination	7	82	8.5%
	After being served, food is not re-served	0	82	0.0%

Discussion for Figure S-3

The food safety procedures for the contaminated equipment/protection from contamination risk factor that are most in need of attention include the following:

- Separating raw animal foods from ready-to-eat foods (25.7%)
- Cleaning and sanitizing food-contact surfaces and utensils (18.3%)
- Separating raw animal foods from each other (18.0%)

Separation of Raw Animal Foods from Ready-to-Eat Foods

Raw animal foods are a potential source of contamination in any food operation. Storing raw animal foods above or in close proximity to ready-to-eat foods increases the potential for food to become contaminated. To prevent cross-contamination, raw animal foods should also be separated by species based on required minimum cooking temperatures. Required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters may vary with different types of raw animal foods. Having organized, designated areas for the safe storage of different raw animal products and better use of containers, trays, and dividers will help prevent cross-contamination of foods.

Preventing cross-contamination between raw animal foods and ready-to-eat foods extends to the food preparation area. Designated, separate food preparation areas should be provided for raw and ready-to-eat products. If common preparation areas must be used, then procedures must be in place to ensure proper cleaning and sanitizing between products.

Cleaning and Sanitizing

Proper cleaning and sanitization of food-contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and clean-in-place equipment such as slicers and mixers are cleaned and sanitized between uses.

The high Out of Compliance percentage for cleaning and sanitizing food-contact surfaces and utensils indicates a weakness in seafood department management systems designed to prevent cross-contamination.

<u>Discussion for the Food from Unsafe Sources</u>

Table 27

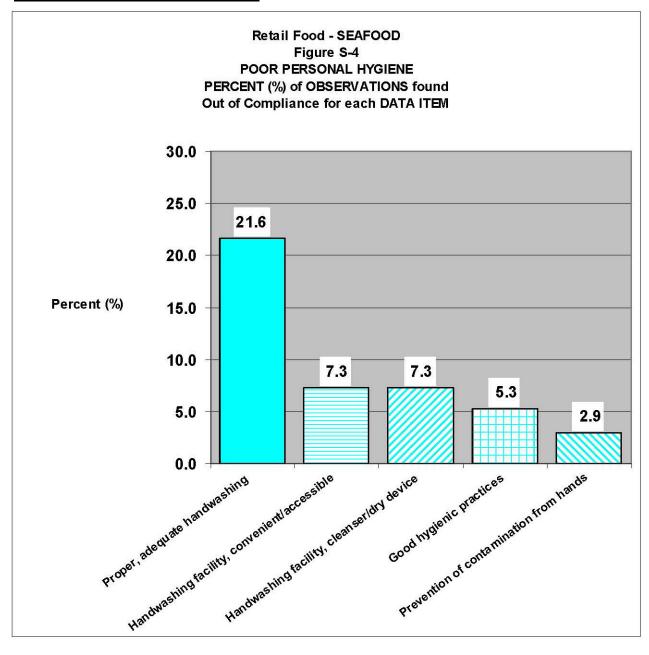
Assessment of the Food from Unsafe Sources Risk Factor - SEAFOOD

Shellstock Tags Retained for 90 Days

# Observations		
16	60	26.7%

The overall IN Compliance percentages for data items that comprise the food from unsafe sources risk factor was high, indicating effective management of this area. There is one notable exception to this general observation – retention of shellstock tags for 90 days.

Shellfish harvested from contaminated water can harbor harmful bacteria and viruses. Effective monitoring of shellfish sources must be continuous and involve all segments of the industry. Retention of shellstock tags in chronological order for 90 days is not a direct contributing factor to the occurrence of foodborne illness. It is, however, an essential management practice that provides a means for conducting tracebacks to the harvest areas if a food-related illness occurs related to contaminated shellstock. Managers of seafood departments selling oysters, clams, and mussels must review their management systems for tag retention and take corrective action if necessary.



DATA ITEM		# OUT	Total Obs. (IN & OUT)	% OUT
	Proper, adequate handwashing	16	74	21.6%
	Handwashing facility, convenient/accessible	6	82	7.3%
	Handwashing facility, cleanser/drying device	6	82	7.3%
	Good hygienic practices	4	76	5.3%
	Prevention of contamination from hands	2	68	2.9%

Discussion for Figure S-4

The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include the following:

Proper, adequate handwashing (21.6%)

Proper, Adequate Handwashing

Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom, or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities and/or supplies of hand cleanser/drying devices may contribute to a lack of proper handwashing. Also, the temporary placement of mobile equipment in front of the hand sink and the use of handwashing facilities for other purposes can limit employee access and discourage handwashing. Paragraph 2-103.11(D) of the 1997 Food Code specifically addresses the manager's responsibility to routinely monitor the effectiveness of employee handwashing. Reinforcing the importance of handwashing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of handwashing practices.

While handwashing continues to be a primary concern, the results from the 2008 study show a high IN Compliance percentage (97.1%) for preventing direct hand contamination of food in seafood departments. Retail food management in seafood departments appear to be making a concerted effort to eliminate bare hand contact with ready-to-eat foods.

C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

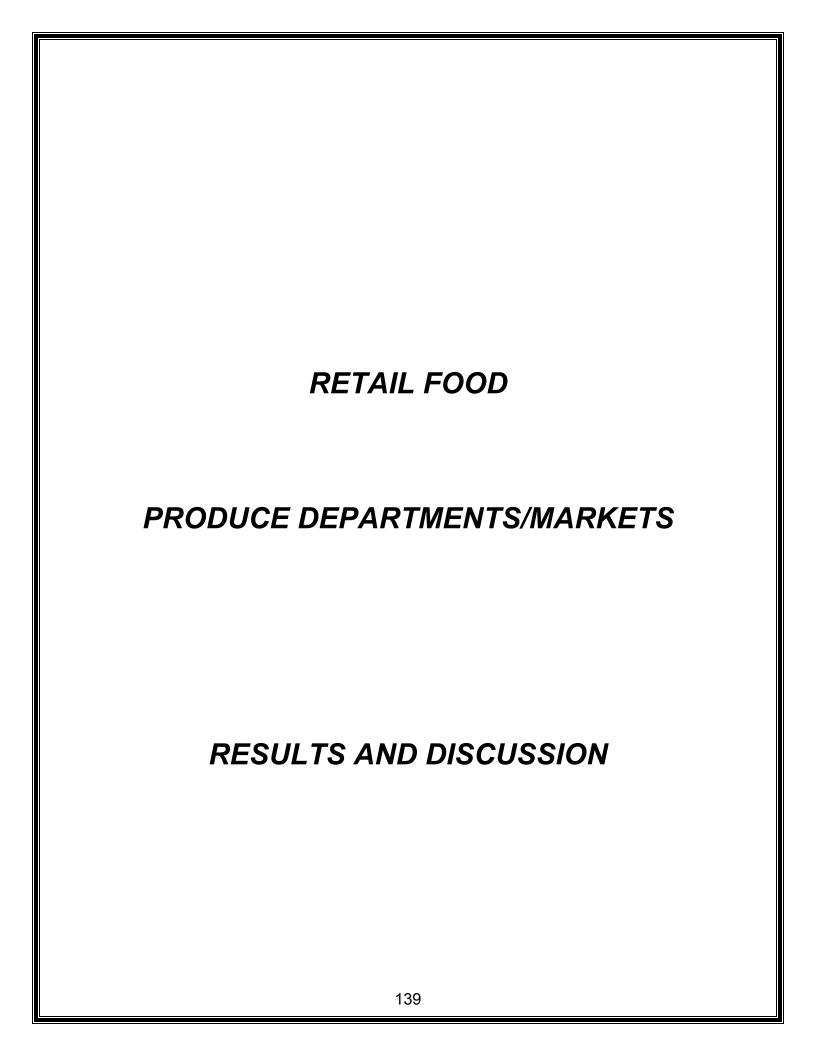
Table 28

Retail Food Store - SEAFOOD

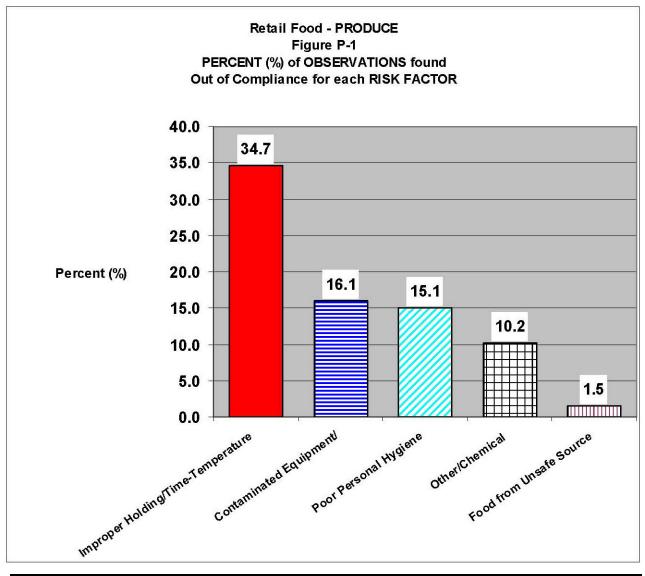
Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)
Improper Holding/ Time & Temperature	Commercially-processed RTE, PHF/TCS Food date marked
	RTE, PHF/TCS Food date marked after 24 hours
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F
	PHF/TCS Food held cold at 41°F or below
	Raw animal food separated from ready-to-eat foods
Contaminated Equipment/ Protection from Contamination	Surfaces/Utensils cleaned/sanitized
Protection from Contamination	Raw animal foods separated from each other
Food from Unsafe Sources	Shellstock tags retained for 90 days
Poor Personal Hygiene	Proper, adequate handwashing

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A. Percent of observations found Out of Compliance for each RISK FACTOR



FOODBORNE ILLNESS RISK FACTOR	# OUT	Total Obs. (IN & OUT)	% OUT
Improper Holding/Time & Temperature	86	248	34.7%
Contaminated Equipment/Protection from Contamination	48	299	16.1%
Poor Personal Hygiene	59	392	15.1%
Other/Chemical	20	196	10.2%
Food from Unsafe Sources	3	194	1.5%

^{*} Data for the Inadequate Cook Risk Factor is not reflected in the Figure P-1 due to a low number of observations (obs.)

Discussion for Figure P-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Contaminated equipment/protection from contamination, poor personal hygiene, and chemical contamination contain data items that warrant attention. Management systems that were implemented to ensure foods were from safe sources appeared to be effective during this data collection period.

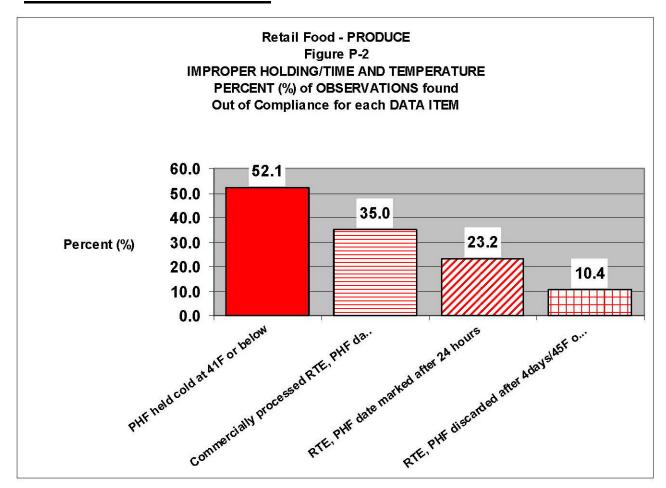
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

For produce departments, the foodborne illness risk factors most in need of attention and corresponding Out of Compliance percentages are as follows:

- Improper Holding/Time Temperature (34.7%)
- Contaminated Equipment (16.1%)
- Poor Personal Hygiene (15.1%)

Figures P-2 through P-4 provide a breakdown of each of these risk factors into data items that represent specific food preparation procedures and employee behaviors in need of attention. These figures provide insight into the relative strengths and weaknesses of the food safety management systems in place in produce departments to control each of the risk factors during the 2008 data collection.

The other/chemical risk factor had one data item of interest. A summary of the results of the Out of Compliance observations for the identification, storage, and use of chemicals/toxic materials data item will be presented as part of the discussion.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	PHF/TCS Food held cold at 41°F or below	50	96	52.1%
	Commercially-processed, RTE, PHF/TCS Food date marked	7	20	35.0%
	RTE, PHF/TCS Food date marked after 24 hours	13	56	23.2%
	RTE, PHF/TCS Food discarded after 4 days/45°F or 7 days/41°F	5	48	10.4%
*	PHF/TCS Food (prepared from ingredients at ambient temp.) is cooled to 41°F or below within 4 hours*	10	17	*
*	Foods received at temperatures according to Law are cooled to 41°F within 4 hours*	1	2	*
*	PHF/TCS Food held hot at 140°F or above*	0	9	*
*	PHF/TCS Food cooled to 70°F on 2 hours/41°F in total of 6 hours*	0	0	*
*	Roasts are held at a temperature of 130°F or above*	0	0	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0	0	*

^{*} These six Improper Holding/Time & Temperature Data Items do not appear in Figure P-2 due to a low number of total observations (obs.)

Discussion for Figure P-2

For the improper holding/time and temperature risk factor, there is a need to review food safety management systems related to the following:

- Maintaining cold holding temperatures for PHF/TCS Food (52.1%)
- Commercially-processed, RTE, PHF/TCS Food date marked (35.0%)
- Date marking of ready-to eat, PHF/TCS Food made on-site (23.2%)

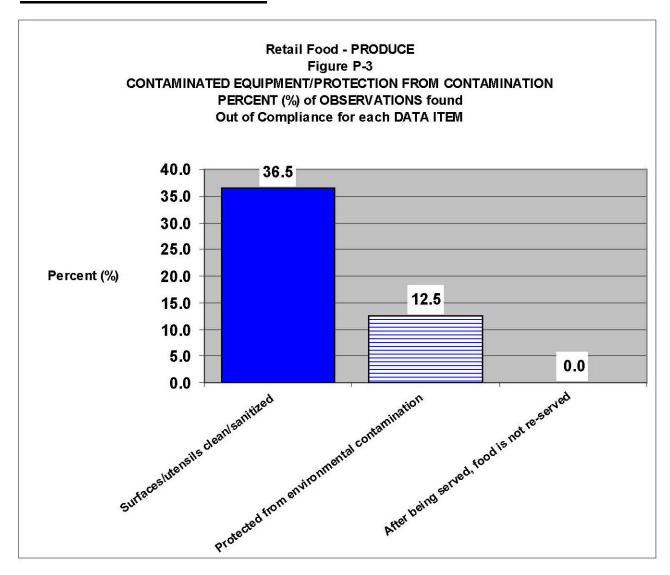
Cold Holding of PHF/TCS Food

Holding PHF/TCS Food at the proper cold temperatures is critical to preventing the growth of bacteria. Equipment, processes, and monitoring procedures related to maintaining temperature control for PHF/TCS Food need to be assessed and corrective actions taken if necessary. Control of cold holding temperatures and date marking provide interlocking protection by slowing the growth of *Listeria monocytogenes* and establishing a time limit for discarding food before the organism can multiply to dangerous levels.

Date Marking

Date marking of refrigerated ready-to-eat, PHF/TCS Food is an important food safety management system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF/TCS Food that has remained in cold storage beyond the parameters described in the *Food Code* prevents foods with a harmful level of *Listeria monocytogenes* from being served.

When cold holding and date marking are viewed in the context of a total food safety system, the potential for bacterial growth increases with each uncontrolled process step. It is essential that each process step be routinely monitored in a manner that enables the manager to take prompt corrective action before an unsafe product reaches the consumer.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	Surfaces/Utensils cleaned/sanitized	35	96	36.5%
	Protected from environmental contamination	12	96	12.5%
	After being served, food is not re-served	0	96	0.0%
*	Raw/RTE foods, separated*	1	7	*
*	Raw animal foods, separated*	0	4	*

^{*} These two Contaminated Equipment/Protection from Contamination Data Items do not appear in Figure P-3 due to a low number of total observations (obs.)

Discussion for Figure P-3

The food safety procedures for the contaminated equipment/protection from contamination risk factor that are most in need of attention include the following:

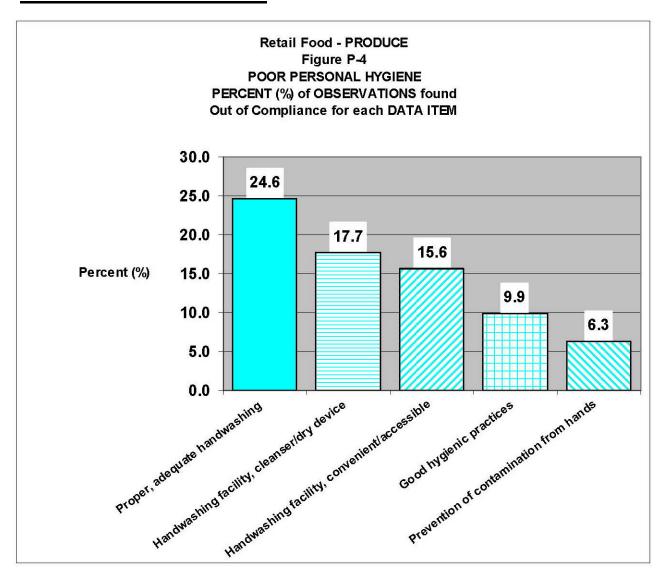
- Cleaning and sanitizing food-contact surfaces and utensils (36.5%)
- Prevention of environmental contamination (12.5%)

Cleaning and Sanitizing

Proper cleaning and sanitization of food-contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and clean-in-place equipment such as slicers and mixers are cleaned and sanitized between uses.

Protection from Environmental Contamination

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, condensate waste, or chemicals. These contaminants may be introduced by other products or equipment stored in close proximity or by persons who are delivering, stocking, or opening packages. Foodservice managers must ensure that standard operating procedures are in place to protect food from environmental contamination from the moment it is received until served or sold to the consumer. Except during cooling, stored products should be covered or wrapped to prevent the entry of microbes and other contaminants.



DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
Proper, adequate handwashing	16	65	24.6%
Handwashing facility, cleanser/drying device	17	96	17.7%
Handwashing facility, convenient/accessible	15	96	15.6%
Good hygienic practices	7	71	9.9%
Prevention of contamination from hands	4	64	6.3%

Discussion for Figure P-4

The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include the following:

- Proper, adequate handwashing (24.6%)
- Handwashing facility, cleanser/drying device (17.7%)
- Handwashing facility, convenient/accessible (15.6%)

Proper, Adequate Handwashing/Handwashing Facilities

Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom, or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities and/or supplies of hand cleanser/drying devices may contribute to a lack of proper handwashing. Also, the temporary placement of mobile equipment in front of the hand sink and the use of handwashing facilities for other purposes can limit employee access and discourage handwashing. Paragraph 2-103.11(D) of the 1997 Food Code specifically addresses the manager's responsibility to routinely monitor the effectiveness of employee handwashing. Reinforcing the importance of handwashing should be supported by a management system that includes proper employee training and monitoring of the frequency and effectiveness of handwashing practices.

While handwashing continues to be a primary concern, the results from the 2008 study show a high IN Compliance percentage (93.7%) for preventing direct hand contamination of ready-to-eat food in produce departments. Retail food managers in produce departments appear to be making a concerted effort to eliminate bare hand contact with ready-to-eat foods.

Discussion for the Other/Chemical Risk Factor

Table 29

Assessment of the Other/Chemical Category - PRODUCE

Poisonous or Toxic Materials are Properly Identified, Stored, and Used

# Observations		
18	96	18.8%

Most of the Out of Compliance observations relating to the other/chemical risk factor were attributed to one data item. The proper identification, storage, and use of cleaners, sanitizers and other chemicals in produce departments are in need of attention. Food safety procedures related to the identification, storage, and use of cleaners, sanitizers, and other chemicals need to be reviewed and revised, if necessary, to address any gaps in the program that may be contributing to the Out of Compliance observations of this data item.

C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

Table 30

Retail Food Store - PRODUCE

Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)			
	PHF/TCS Food held cold at 41°F or below			
Improper Holding/ Time & Temperature	Commercially-processed, RTE, PHF/TCS Food date marked			
	RTE, PHF/TCS Food date marked after 24 hours			
Contaminated Equipment/	Surfaces/Utensils cleaned/sanitized			
Protection from Contamination	Prevention of environmental contamination			
	Proper, adequate handwashing			
Poor Personal Hygiene	Handwashing Facility, cleanser/drying device			
	Handwashing facility, convenient/accessible			
Other/Chemical	Poisonous or toxic materials properly identified, stored, and used			

IV. RECOMMENDATIONS

The following recommendations are based on the findings in this report and are intended to enhance the effectiveness of regulatory and industry retail food protection programs. The recommendations focus on a nationwide effort to reduce the occurrence of foodborne illness risk factors within institutional foodservice, restaurant, and retail food store facilities. Each of the foodborne illness risk factors is comprised of a number of food safety practices and employee behaviors. These practices and behaviors are captured by the individual data items in this report and are based on the food safety provisions of the *1997 FDA Food Code*.

Some changes have occurred in observed compliance in a few of the foodborne illness risk factors since the 1998 and 2003 data collection periods. These changes will be discussed and explored in a separate Trend Analysis Report. However, it is important to note that the risk factors and data items in need of priority attention remain the same as in previous data collection periods for each of the facility types. This is an indication that more action is needed by both the industry and regulatory bodies.

Section III, Results and Discussion, emphasizes the importance of identifying the gaps in the active managerial control of foodborne illness risk factors for each of the facility types. Active managerial control involves purposefully incorporating specific actions and procedures into a food operation by the establishment's management to achieve control over foodborne illness risk factors. If the safety of food is to be significantly improved, foodservice and retail food store managers must establish effective control, monitoring, and supervision over these food safety practices and employee behaviors.

A. <u>Recommendations for Foodservice and Retail Food</u> Industries

Ultimate responsibility for the development and maintenance of effective food safety management systems lies with the management of institutional foodservice, restaurant, and retail food store operations. Individual operators that are responsible for the day-to-day management of these facilities play a key role in preventing foodborne illness. The establishment manager's role in preventing foodborne illness should be raised to a new level of awareness.

Food safety management systems can take many forms. Every establishment has some set pattern of procedures, even if it is simply described as "the way we do things." Some establishments have implemented effective food safety management systems by establishing controls for food preparation methods and monitoring processes common to their operation. Many others, however, continue to rely on vague, unmonitored procedures. At a minimum, an operator's food safety management system should be based on achieving the same level of safety established by the critical limits in the *Food Code*. Recommendations for industry managers include the following:

Develop and implement written Standard Operating Procedures (SOPs) that
address the risk factors. These SOPs should detail the monitoring and corrective
action procedures necessary for time/temperature control of potentially hazardous

food and cooking of raw animal foods, good personal hygiene, and prevention of cross-contamination. The SOPs should include the critical limits, or the minimum or maximum parameters that must be met to ensure that food safety hazards are controlled at critical process steps. Responsibility for measuring the critical limits should be assigned to specific employees or employee positions. These SOPs should be specific to the operation and tested by management to ensure that the procedures are effective for controlling the risk factor. Training on the implementation of SOPs should be included in employee orientation and in periodic refresher training.

- Provide the necessary resources, equipment, and supplies to implement the SOPs. Items such as temperature measurement devices preferably thermocouples, temperature logs, the availability of hand soap and towels at each handwashing station, and the use of chemical sanitizers at the required strength along with chemical test papers are crucial to the successful control of specific risk factors.
- Verify that monitoring procedures are being followed by employees.
 Monitoring procedures will only be effective if employees are given the knowledge, skills, and responsibility for specific food safety tasks. Management should verify, through active daily oversight, that critical processes are being monitored by employees. Ultimately, it is the establishment manager's responsibility to verify that monitoring is taking place as outlined in the SOPs and that employees are following the SOPs as they were written.
- Identify methods to routinely assess the effectiveness of the SOPs. This assessment approach could be based on an internal review, regulatory inspection results, or third party evaluation. Managers should review SOPs at least annually to determine whether the SOPs as written are still effective or whether changes in the operation, ingredients, equipment, or personnel have triggered the need for revisions. Regulatory inspections or third party evaluations that indicate failure to control cook temperatures, cooling, hot or cold hold temperatures, handwashing, cross contamination, or other risk factor items should motivate managers to examine SOPs and monitoring procedures for effectiveness and to implement immediate corrective actions necessary to produce safe food. The manager's response to out-of-control risk factors will determine the level of public health protection provided in any given facility.

The importance of each of these recommendations is reinforced by the results of the 2008 data collection on the occurrence of risk factors. The percentage of observations that were found to be Out of Compliance with data items related to handwashing, barehand contact with ready to eat foods, time/temperature control, and contaminated equipment remained high in 2008 for many of the facility types. This suggests that industry efforts to achieve active managerial control over these risk factors and to adequately train employees still need to be improved. Managing risk factors must be a fully integrated part of every business operation if the industry is to significantly reduce the risk of foodborne illness.

Section III, Results and Discussion, provides a national overview of the food safety practices and procedures most in need of improvement for each of the nine facility types. This information is provided as a summary table following the analysis and discussion for each facility type. As a start, industry operators should evaluate how well they are controlling these particular data items in their own operations. When weaknesses are discovered in their respective food safety management systems, action must be initiated to correct the immediate problem and to ensure long-term control of the risk factor.

To assist industry in the development of management systems designed to control foodborne illness risk factors, FDA has developed a document, *Managing Food Safety:* A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments. The direct FDA web site link to this document is:

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACC PPrinciples/Operators/default.htm.

B. <u>Recommendations for Regulatory Retail Food Protection</u> <u>Programs</u>

The high percentage of observations found to be Out of Compliance with many of the data items covered in this study indicates that regulatory agencies need to do more to affect change in food safety practices and behaviors in foodservice and retail food establishments. In conjunction with their industry partners, regulatory agencies should focus their efforts on reducing the occurrence of the risk factors highlighted in Section III of this report. A review of the Summary Tables for the Foodborne Illness Risk Factors and Data Items in Need of Priority Attention for each of the nine facility types would be a good starting point for jurisdictions intent on facilitating improvement in food safety systems. The recommendations below may assist agencies toward establishing a food safety improvement goal.

Annex 5 of the 2009 FDA Food Code provides regulatory professionals with approaches for conducting risk based inspections within retail food store and foodservice establishments. Additional guidance for assisting the industry assess the effectiveness of their food safety management systems is contained in FDA's, *Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems.* The direct FDA web site link to this document is:

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACC PPrinciples/Regulators/default.htm.

The document contains more detailed information on each of the quality program recommendations that are discussed in this report.

Conducting quality, risk-based inspections

Develop procedures that focus the inspection process on the risk factors that most often contribute to foodborne illness. The risk factors should be the primary focus of every inspection. Inspectors must understand the public health reasons underlying the regulatory requirements and be able to correctly apply the requirements for the control of each risk factor. Each jurisdiction has limited resources and time to spend on-site in each facility, so inspectors must focus on the behaviors and practices that most often contribute to foodborne illness. More time should be spent observing employee practices such as handwashing, ready-to-eat food preparation practices, cooling of foods, and clean-up procedures between operations. Not only will the inspection time be better spent, but the results of the inspection will be more valuable for the jurisdiction, the industry, and the consumer.

Provide appropriate Inspection tools to inspectors. Use of an inspection form that directs the inspector to routinely document the compliance status (IN Compliance, Out of Compliance, Not Observed, and Not Applicable) for practices and behaviors related to the risk factors is recommended. The risk factors applicable to the operation should be evaluated during each inspection. An inspector must also be properly equipped with other necessary inspection tools such as accurate temperature measuring devices including thermocouples or digital thermometers, alcohol swabs, and sanitizer concentration test kits to assess an establishment's compliance with certain risk factors. Bi-metal stem thermometers are not suitable for measuring thin foods or low-moisture foods and are too slow to be efficient, especially considering the number of temperatures that should be taken during an inspection.

Consider providing alternative work schedules to accommodate varied timing of inspections. The time of day that inspections are conducted may need to be varied based on the food facility operations. Inspectors may need flexible schedules to ensure observations of critical food preparation practices that routinely occur before or after the inspector's traditional working hours. An example of a common procedure that occurs outside an inspector's traditional working hours is the cooling of PHF/TCS Food. Cooling is common to complex food preparation and frequently occurs at the close-of-business or during early-morning production cycles. Cooling is also one procedure that should be observed more frequently than it is currently. Business start-up procedures such as rapid reheating of previously cooked food items are also difficult to observe without varied inspector work schedules.

Providing on-site education and achieving voluntary compliance

Recognize and make use of any existing industry quality assurance (QA) or training programs. Inspectors should become familiar with an establishment's existing QA and employee training programs and reinforce components of these programs that lead to active managerial control of risk factors. An inspector that is familiar with an establishment's control procedures and monitoring practices for risk factors can inspect more effectively than one who must approach each operation as an unknown situation. Time spent learning an establishment's system can allow an inspector to focus on potential weaknesses and offer suggestions for strengthening an existing food safety management system.

Establish an open dialogue with operators. Inspectors should discuss out-of-control risk factors with establishment operators and suggest appropriate control measures suitable to the individual operation. Many times interpretations of inspection observations cannot be made accurately without an interactive dialogue with food employees or managers. For example, cooling and cold holding violations at times cannot be distinguished without information supplied by the operator. In order to effectively perform risk-based inspections, the importance of establishing a rapport and possessing good communication skills cannot be overemphasized.

Obtain immediate corrective action. Inspectors should require immediate corrective action for risk factors found to be Out of Compliance with regulatory requirements. Immediate corrective action should be verified and documented before the inspector leaves the facility. This practice not only emphasizes the importance of compliance with these requirements to operators, but also protects the public from the potential consequences of out-of-control risk factors.

Assist operators with developing SOPs and risk control plans. Regulators should conduct on-site meetings with <u>new</u> permit holders to evaluate active management control of foodborne illness risk factors. Early intervention to ensure managers implement appropriate training, monitoring, and oversight will improve long-term compliance. Consultative meetings provide inspectors an opportunity to assist operators in developing management plans such as risk control plans that describe the specific actions to be taken to achieve long-term control of Out of Compliance risk factors. A risk control plan is a short, concisely written management plan developed by the retail or foodservice operator with input from the regulatory authority for a specific risk factor such as cooling or cooking. Risk control plans can be used as both education and compliance tools for addressing out-of-control risk factors.

Develop intervention strategies. Jurisdictions should develop other intervention strategies to address out-of-control risk factors. Initiatives to bring greater awareness of the role that risk factors play in foodborne illness and facilitate greater compliance should be instituted. Examples could be monthly educational campaigns or jurisdiction-wide emphasis on compliance with selected risk factors. Coordinated intervention strategies would serve to raise awareness of the risk of not following proper safe handling practices and would focus inspection, enforcement, or educational efforts on risk factors most in need of attention.

Implementing a consistent and effective enforcement protocol

Develop enforcement procedures and strategies. Having written, well-defined, step-by-step procedures for bringing enforcement actions against facilities that repeatedly fail to achieve compliance with requirements related to foodborne illness risk factors is essential. It is important that each jurisdiction have a systematic process for taking action when it is warranted, and that inspectors be well-versed in their expected role in the enforcement process. While education and assistance are important duties of the inspector and should be the first tools used to gain compliance, a jurisdiction must have appropriate enforcement tools necessary to protect the consuming public.

Enforcement efforts must address the underlying causes of non-compliance. Out of control risk factors are often the result of a lack of attention to critical processes by the permit holder or person in charge. Enforcement directed at immediate correction alone will not produce long-term compliance. An effective enforcement strategy must address failures by managers to perform required monitoring, training and oversight duties. These duties are contained in Section 2-103.11 of the Food Code. Whenever a risk factor violation is cited for non-compliance, the appropriate management control for that risk factor should also be evaluated for compliance.

Ensure credibility. The enforcement process must be applied fairly, uniformly, and with consistency when risk factors are repeatedly out-of-control.

Continuous program improvement

The recommendations described above are captured in more detail in the *Voluntary National Retail Food Regulatory Program Standards (Program Standards)*. The Program Standards apply to the operation and management of a retail food regulatory program that is focused on the reduction of foodborne illness risk factors and the promotion of active managerial control of these risk factors. Through a process of self-assessment, agencies use the Program Standards to evaluate the effectiveness of their food safety program.

While the nine Program Standards viewed together represent a highly effective and developed retail food safety program, any regulatory program can use the Program Standards as a foundation to build upon through a continuous improvement process. Managers of regulatory inspection programs are encouraged to review existing practices and procedures against the criteria in the Program Standards to ensure that current program activities target reducing the occurrence of those risk factors identified in Section III, Results and Discussion.

The Voluntary National Retail Food Regulatory Program Standards can be accessed and downloaded from FDA's web site at:

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm1249 68.htm

The Program Standards encourage state and local jurisdictions to establish studies on the occurrence of foodborne illness risk factors that are specific to their geographic area of responsibility. To assist agencies interested in conducting risk factor studies of their own, FDA has prepared a manual and an accompanying software program designed to assist with the management of the data collected. Information about the data collection manual and software package can be obtained from an FDA Regional Retail Food Specialist.

V. FIELD AND STATISTICAL LIMITATIONS

How a research project is designed and implemented impacts the interpretation of the data. Earlier in this report, some internal and external factors influencing the design and scope of the project were discussed. All field studies involving data analysis have uncontrollable factors that place limitations on how the data is collected, analyzed, and reported. These factors can be placed in two broad categories:

- A. Field Operational Limitations
- B. Statistical Limitations

A. Field Operational Limitations

Attempts were made to observe the same risk-related data items that appear on the data collection form presented under Methodology, Section II, at each establishment. The foodservice and retail food industry is dynamic. There is no set pattern of operation within foodservice and retail food store facilities upon which data collections can be scheduled to be assured of observing all the data items. This results in variations in total number of observations for each of the data items.

The framework that Specialists used to collect the data mirrored the process currently employed by state and local inspectors conducting routine inspections. The factors that impacted the ability of Specialists to observe the specific employee food safety practices and behaviors included establishment type, the season of the year, the time of day the survey was conducted, and the length of time available for each inspection.

Some data items that had a low number of observations included the following:

- Foods received according to law, cooled to 41°F (5°C) within 4 hours
- Cooked PHF/TCS Food cooled from 140°F (60°C) to 70°F (21°C) within 2 hours and from 140°F (60°C) to 41°F (5°C) in a total of 6 hours
- PHF/TCS Food (from ambient ingredients) cooled to 41°F (5°C) or below within 4 hours
- Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes
- Wild game animals cooked to 165°F (74°C) for 15 seconds
- As required, written documentation of parasite destruction maintained for 90 days for fish products
- Critical Control Point (CCP) monitoring records maintained in accordance with HACCP Plan when required

Some of these data items require a significant period of time to assess compliance with regard to time/temperature standards. They may also involve processes or operational steps that occur outside traditional regulatory work hours; thus, documentation of these steps or processes may not have been available at the time of the inspection. Other data items related to foods that are not commonly found on the menus of the facility types inspected included items such as cooking whole roasts or wild game animals.

B. Statistical Limitations

Sample Design

Since a random selection of all facility types in the United States would not be feasible from a financial or logistical perspective, an alternative method was selected. Comparison set lists were developed in each of the five FDA Regions located throughout the country. The current picture of compliance with the risk factors reflects the entire U.S. only to the extent that the comparison set lists are representative of the overall industry.

Because the facilities were not selected randomly from the entire U.S., statistical estimates of the precision with which they estimate the entire U.S. for each facility type cannot be provided. We only have a common sense opinion that since the Specialists are spread across the U.S. we have a reasonable approximation of the compliance picture of the nation as a whole.

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

A challenge inherent to measuring trends is uncontrolled variation in samples. The design of this project attempted to reduce this variation by the use of the comparison set lists. A typical comparison set list consisted of ten or more establishments of the same facility type in the same general geographic area. Where the number of establishments for a facility type within a designated geographic area was small, such as with nursing homes and hospitals, much bigger geographic areas were required than for facility types that were more numerous. In areas with limited numbers of nursing homes and hospitals, a comparison set list included a minimum of four establishments.

The establishments in each comparison set list were placed in alphabetical order and sequentially numbered. The Specialists then used a table of random numbers, supplied by CFSAN's Biostatistics Branch, to select the particular establishment to inspect. The comparison set lists compiled by the Specialists, have been archived. A different establishment was to be randomly selected from the same comparison set list for each data collection period, thus reducing selection bias.

This project was designed to examine patterns on the occurrence of foodborne illness risk factors within the foodservice and retail food industry using multiple data collection periods. The way the samples were selected and the size of the dataset do not support comparisons of individual Specialists' geographical areas, states, cities, or even regions of the U.S.

In addition, the project is not designed to support comparisons of different chains of fast food restaurants or grocery stores. There is no statistical justification for examining

reduced sets of results particular to, for example, two chains of restaurants and drawing conclusions from the differences.

Comparing data over time

A summary of the observations made during the 2008 data collection period for ALL data items for each facility type is presented on pages 178-213. Although the data collected in 2008 is part of a larger study designed to measure changes in the IN Compliance percentages over time, this data collection period provides only one of three data points in the study progression. This report makes no attempt to analyze the difference among IN Compliance percentages in the 1998, 2003, and 2008 results.

FDA plans to release a separate trend analysis report covering the 1998-2008 span of this study in early 2010. Using the data from the 1998, 2003, and 2008 data collection periods, FDA will evaluate trends and determine whether progress is being made toward the goals of reducing the occurrence of foodborne illness risk factors.

At the beginning of the study design, it was anticipated that the number of observable and applicable responses for each data item would vary. The total number of observations for each data item is likely to change from one data collection period to another. The variation in the number of observations can make it difficult to draw statistical conclusions between any two data collection periods. Changes in the number of observations of data items may be attributed to the following:

- Sample variations
- Changes in industry practices
- Quality assurance issues associated with the data collection tool

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

Changes in industry practices. If a change in an overall industry practice results in more inspectors marking not applicable (NA) rather than IN or Out of Compliance, then there may be a change in the total number of observations for a given data item from one data collection period to the next. This may result in a corresponding change in the relative weight of that data item in the compliance percentage for the relevant risk factor. For example, if numerous establishments have shifted from using raw shell eggs to using pasteurized egg products, the number of observations related to Inadequate Cooking will go down from one data collection period to the next. Therefore, a lower Out of Compliance percentage for the Inadequate Cooking risk factor may not be reported even though the new industry practice represents improved active managerial control.

Quality assurance. After the 1998 and 2003 data collection periods, a thorough quality assurance review of the marking instructions was conducted for each data item. There were a few data items from the original data collection period for which it was necessary to clarify the marking instructions, and in several cases, slight modifications to the data

items were necessary. Clarifying marking instructions and modifying data items can affect the number of observations for specific data items and, in turn, the compliance percentages for the risk factors and data items for subsequent data collection periods.

Impact of changes in number of observations from one data collection period to another. Increases or decreases in the number of observations made for a given data item will have an impact on IN Compliance percentages for the corresponding risk factor. All else being equal, a decrease in total observations for a high IN Compliance data item can offset an increase in the IN Compliance percentages for other data items, since several data items are combined to represent a single risk factor. For example, consider a risk factor that is comprised of two data items – Item A and Item B. The following chart provides a fictitious summary of observations made of each of the data items in 1998 and 2003.

RISK FACTOR

		1998		2003				
	# IN	TOTAL Obs.	% IN	# IN	TOTAL Obs.	% IN		
Data Item A	50	100	50%	50	100	50%		
Data Item B	100	100	100%	50	50	100%		
Overall	150	200	75%	100	150	67%		

In the above illustration, Data Item A has the same total number of observations (100) and total number of IN Compliance observations (50) for both 1998 and 2003. For each of these data collection periods the IN Compliance percentage for Data Item A is 50%. Data Item B has a 100% IN Compliance percentage for both 1998 and 2003. In 2003, however, 50 less observations were made of Data Item B.

The IN Compliance percentages for Data Item A (50%) and Data Item B (100%) were exactly the same for both data collection periods. The impact of the 50 less observations for the high IN Compliance data Item (B) lowered the overall IN Compliance percentage for the risk factor from 75% in 1998 to 67% in 2003.

If an attempt is made to compare the 2003 IN Compliance percentage (67%) with the 1998 IN Compliance percentage (75%), an erroneous conclusion might be made that the degree of control of this risk factor had regressed by 8%. The underlying cause for the 8% regression, however, is not due to less control of the risk factor but rather a result of fewer observations (50 less) for data item B which in both data collection periods had an IN Compliance percentage of 100%.

The potential impact of the above scenario on the different data collection periods in this study can be compounded because the Overall IN Compliance percentage upon which trends are being measured is a weighted average of the IN Compliance percentages for forty-two data items. The weights are the number of observations for each data item and are not identical between data collection periods; therefore, making statistical

comparisons between data collection periods becomes difficult. The impact of this weighting issue will be examined for each of the data collection periods and addressed in the trend analysis report (to be completed in 2010) that will examine improvement or regression of industry management control of foodborne illness risk factors and data items.

VI. ADDITIONAL AREAS OF STUDY

A. <u>Impact of Certified Food Protection Managers on the Control of Foodborne Illness Risk Factors</u>

Minimizing the occurrence of foodborne illness risk factors in a foodservice or retail food operation does not happen by accident. The importance of having knowledgeable and effective managers on-site during all hours of operation cannot be overstated. The person in charge of a food establishment is responsible for ensuring that policies and procedures that prevent the transmission of foodborne illness are established, routinely followed, and that corrective actions are taken, as needed, to protect the health of the consumer.

If the person in charge is knowledgeable about the relationship between the prevention of foodborne illness and the various operations, practices, and behaviors that take place in the food establishment, then he or she will be in a far better position to exert active managerial control over foodborne illness risk factors. Encouraging or requiring certification as a food protection manager is one means by which the food industry and regulatory authorities have sought to increase establishment managers' knowledge of food safety.

During the 2008 data collection, Specialists were instructed to determine whether the facility being inspected had a Certified Food Protection Manager on-site. For the purposes of this study, Specialists were instructed to circle "YES" on the Certified Food Protection Manager line on the facility information portion of the Data Collection Form if the person in charge had been certified by any one of four certification programs whose examinations had been recognized by the Conference for Food Protection (CFP) at the time the data collection effort started. If the person in charge was not a Certified Food Protection Manager or had been certified by an organization not recognized by the CFP, Specialists were instructed to circle "NO" on the Data Collection Form.

One reason this information was collected was to get a better picture of the extent to which Certified Food Protection Managers are present in the various facility types during hours of operation. The *Food Code* does not mandate certification but does recognize food protection manager certification by an accredited program as one means by which a person-in-charge can demonstrate knowledge of foodborne illness prevention, application of Hazard Analysis and Critical Control Point (HACCP) principles, and the requirements of the *Food Code*. The number of inspected establishments of each facility type with and without a Certified Food Protection Manager (as determined by the criteria described above) is shown in Table 31 on page 161.

Inspected Facilities With and Without a Certified Food Protection Manager

Table 31

	# Of Inspected Facilities WITHOUT Certified Food Protection Manager	# Of Inspected Facilities WITH Certified Food Protection Manager	% Of Inspected Facilities WITH Certified Food Protection Manager
Hospital	13	77	85.6%
Nursing Home	34	59	63.4%
Elementary Schools	34	59	63.4%
Fast Food Restaurants	39	64	62.1%
Full Service Restaurants	48	48	50.0%
Delis	31	67	68.4%
Meat & Poultry	36	63	63.6%
Seafood	28	54	65.9%
Produce	31	65	67.7%

Impact of Certified Food Protection Manager for each Facility Type

This study was not designed to definitively determine whether having a Certified Food Protection Manager on-site has an effect on the overall IN Compliance percentages of establishments. However, the results of the study indicated that the presence of a Certified Food Protection Manager is positively correlated to the overall IN Compliance percentages in certain facility types. Four facility types had overall IN Compliance percentages (all 42 data items combined) that were significantly higher in establishments with a Certified Food Protection Manager than in establishments without a Certified Food Protection Manager. These facility types are identified with **bold type** in Table 32. In the five remaining facility types, the differences were not statistically significant¹.

When assessing the statistical significance of the differences between facility types that have certified food protection managers and non certified food protection managers, the Bonferroni adjustment procedure for multiple comparisons was used. This method requires that the probability of committing one or more type 1 errors is .05. Since there are nine facility types, nine comparisons were made resulting in a type 1 error rate to be far smaller than .05 for each comparison. In fact, the p-value required to conclude that a significant difference existed was .0056 or less.

Table 32
Impact of Manager Certification on the Overall Percent IN Compliance by Facility
Type

(2008 Data Collection Form: Sections 1-16 (42 Data Items)*

	Mana	ger N	on Cer	tified	Manager Certified				D:((
Facility Type	Total Obs.	# IN	# OUT	% IN	Total Obs.	# IN	# OUT	% IN	Difference (% IN)
Hospitals	276	211	65	76.4	1610	1317	293	81.8	5.4
Nursing Homes	680	561	119	82.5	1171	967	204	82.6	0.1
Elementary Schools	543	459	84	84.5	983	819	164	83.3	- 1.2
Fast Food Restaurants	667	496	171	74.4	1223	974	249	79.6	5.3
Full Service Restaurants	959	555	404	57.9	1038	731	307	70.4	12.6
Delis	602	386	216	64.1	1279	1009	270	78.9	14.8
Meat and Poultry	498	425	73	85.3	877	791	86	90.2	4.9
Seafood	437	356	81	81.5	905	795	110	87.8	6.4
Produce	409	322	87	78.7	923	792	131	85.8	7.1

^{*} The figures in Table 32 do not include the Supplemental Data Items found in Sections 17-23 of the Data Collection Form (pages 25-26).

NOTE: <u>BOLDED</u> facility types had overall IN Compliance percentages that were significantly higher in establishments with a Certified Food Protection Manager

Impact of Certified Food Protection Manager on the Risk Factors

Table 33 presents the risk factors for which the percent IN Compliance for establishments with Certified Food Protection Managers was significantly higher than those without Certified Food Protection Managers. Poor Personal Hygiene, Improper Holding/Time and Temperature, and Contaminated Equipment/Prevention from Contamination appear to be the risk factors for which the presence of a certified manager had the most positive correlation.

Table 33

Risk Factors with Statistically Significant Differences Between Establishments

WITH and WITHOUT a Certified Food Protection Manager

Facility Type	Risk Factor
Full Service Restaurants	 Poor Personal Hygiene Contaminated Equipment/Protection from Contamination Improper Holding/Time and Temperature
Delis	Poor Personal HygieneImproper Holding/Time and Temperature

Specific data for each of the five risk factors and the "other/chemical" category are presented in Tables 34A – 34F. These tables show the percent IN Compliance recorded in establishments that had a Certified Food Protection Manager present and those that did not. There was no risk factor for which the IN Compliance percentage for establishments without a certified manager exceeded the percentage for establishments with a certified manager in a statistically significant manner²

²The same multiple comparison method was used to assess the statistical significance of the differences between risk factors within the different facility types that have certified food protection managers and non-certified food protection managers. Since there are approximately fifty-four comparisons (there are six risk factors for each facility type and nine facility types; however, for several of the risk factors inadequate sample size or violation of the rules relating to the normal approximation of the sampling distribution of the sample proportion made the statistical test inappropriate) we required a p-value of .001 or less to conclude that a significant difference existed. In this case, the probability of committing one or more type 1 errors is .05.

Table 34A

Food from Unsafe Source

Effect of Manager Certification on Percent IN Compliance by Facility Type

	Total Obs.	Total IN	Total OUT	% IN	Total Obs.	Total IN	Total OUT	% IN	
Hospitals	28	26	2	92.86	165	158	7	95.76	2.90
Nursing Homes	70	70	0	100.00	122	118	4	96.72	-3.28
Elementary Schools	69	65	4	94.20	118	115	3	97.46	3.26
Fast Food Restaurants	79	77	2	97.47	130	127	3	97.69	0.22
Full Service Restaurants	117	102	15	87.18	125	111	14	88.80	1.62
Delis	66	63	3	95.45	144	138	6	95.83	0.38
Meat and Poultry	84	80	4	95.24	136	135	1	99.26	4.02
Seafood	92	77	15	83.70	207	188	19	90.82	7.12
Produce	62	60	2	96.80	132	131	1	99.20	2.40

Table 34B

Inadequate Cooking

Effect of Manager Certification on Percent IN Compliance by Facility Type

F 111			nager ertified			Maı Cer	D:(()		
Facility Type	Total Obs.	Total IN	Total OUT	% IN	Total Obs.	Total IN	Total OUT	% IN	Difference (% IN)
Hospitals	34	34	0	100.00	188	183	5	97.34	-2.66
Nursing Homes	72	65	7	90.28	94	85	9	90.43	0.15
Elementary Schools	29	27	2	93.10	47	40	7	85.11	-7.99
		ı				ı			
Fast Food Restaurants	53	47	6	88.68	123	116	7	94.31	5.63
Full Service Restaurants	102	90	12	88.24	125	102	23	81.60	-6.64
Delis	43	38	5	88.37	84	77	7	91.67	3.30
Meat and Poultry	0	0	0	NA	1	1	0	100.00	NA
Seafood	0	0	0	NA	3	3	0	100.00	NA
Produce	0	0	0	NA	3	1	2	33.33	NA

Table 34C

Improper Holding/Time and Temperature

Effect of Manager Certification on Percent IN Compliance by Facility Type

	Manager Not Certified				Manager Certified				D:((
Facility Type	Total Obs.	Total IN	Total OUT	% IN	Total Obs.	Total IN	Total OUT	% IN	Difference (% IN)
Hospitals	69	43	26	62.32	414	265	149	64.01	1.69
Nursing Homes	171	120	51	70.18	312	222	90	71.15	0.97
Elementary Schools	126	89	37	70.63	238	175	63	73.53	2.90
Fast Food Restaurants	144	79	65	54.86	296	193	103	65.20	10.34
Full Service Restaurants	216	74	142	34.26	261	142	119	54.41	20.15
		l							
Delis	155	47	108	30.32	335	194	141	57.91	27.59
Meat and Poultry	53	35	18	66.04	103	90	13	87.38	21.34
Seafood	65	43	22	66.15	129	88	41	68.22	2.07
Produce	65	41	24	63.08	183	121	62	66.12	3.04

NOTE: <u>BOLDED</u> facility types had overall IN Compliance percentages that were significantly higher in establishments with a Certified Food Protection Manager

Table 34D

Contamination of Equipment/Protection from Contamination

Effect of Manager Certification on Percent IN Compliance by Facility Type

E	Manager Not Certified					Man Cert	D.M.		
Facility Type	Total Obs.	Total IN	Total OUT	% IN	Total Obs.	Total IN	Total OUT	% IN	Difference (% IN)
Hospitals	65	47	18	72.31	378	318	60	84.13	11.82
Nursing Homes	167	135	32	80.84	292	247	45	84.59	3.75
Elementary Schools	117	101	16	86.32	222	188	34	84.68	-1.64
						T			
Fast Food Restaurants	166	134	32	80.72	289	242	47	83.74	3.02
Full Service Restaurants	234	135	99	57.69	237	171	66	72.15	14.46
		l	l			l		l	
Delis	151	113	38	74.83	313	264	49	84.35	9.52
Meat and Poultry	169	136	33	80.47	301	254	47	84.39	3.92
Seafood	127	102	25	80.31	254	227	27	89.37	9.06
Produce	93	74	19	79.57	206	177	29	85.92	6.35

NOTE: <u>BOLDED</u> facility type had overall IN Compliance percentages that were significantly higher in establishments with a Certified Food Protection Manager

Table 34E

Poor Personal Hygiene

Effect of Manager Certification on Percent IN Compliance by Facility Type

	Manager Not Certified				Manager Certified				
Facility Type	Total Obs.	Total IN	Total OUT	% IN	Total Obs.	Total IN	Total OUT	% IN	Difference (% IN)
Hospitals	65	47	18	72.31	384	325	59	84.64	12.33
Nursing Homes	165	141	24	85.45	290	241	49	83.10	-2.35
Elementary Schools	168	145	23	86.31	295	249	46	84.41	-1.90
				1					
Fast Food Restaurants	186	134	52	72.04	319	249	70	78.06	6.02
Full Service Restaurants	237	119	118	50.21	240	163	77	67.92	17.71
Delis	153	107	46	69.93	335	281	54	83.88	13.95
Meat and Poultry	156	143	13	91.67	273	257	16	94.14	2.47
Seafood	125	108	17	86.40	257	240	17	93.39	6.99
Produce	127	96	31	75.59	265	237	28	89.43	13.84

NOTE: <u>BOLDED</u> facility types had overall IN Compliance percentages that were significantly higher in establishments with a Certified Food Protection Manager

Table 34F

Other/Chemical

Effect of Manager Certification on Percent IN Compliance by Facility Type

			ager ertified		Manager Certified				
Facility Type	Total Obs.	Total IN	Total OUT	% IN	Total Obs.	Total IN	Total OUT	% IN	Difference (% IN)
Hospitals	15	14	1	93.33	81	68	13	83.95	-9.38
Nursing Homes	35	30	5	85.71	61	54	7	88.52	2.81
Elementary Schools	34	32	2	94.12	63	52	11	82.54	-11.58
				1				I I	
Fast Food Restaurants	39	25	14	64.10	66	47	19	71.21	7.11
Full Service Restaurants	53	35	18	66.04	50	42	8	84.00	17.96
		l	l				l	l .	
Delis	34	18	16	52.94	68	55	13	80.88	27.94
Meat and Poultry	36	31	5	86.11	63	54	9	85.71	-0.40
Seafood	28	26	2	92.86	55	49	6	89.09	-3.77
Produce	62	51	11	82.26	134	125	9	93.28	11.02

B. <u>Supplemental Data Items</u>

The original 42 data items used for the 1998 baseline data collection were retained in the 2003 and 2008 data collections; however, beginning with the 2003 data collection, additional data items were added to gain a better understanding of various industry practices and procedures not addressed in the 1998 baseline collection project. These supplemental data items address practices and procedures related to either foodborne illness risk factors or *Food Code* interventions. The following are subject areas that were included in the supplemental data collection in 2003 and 2008:

- Cooking temperatures for pork, ratites, and injected meats
- Hot holding of potentially hazardous food
- Employee health
- Juice treatment
- Cooling and cold holding of raw shell eggs
- Special requirements for establishments serving highly susceptible populations

Cooking Temperatures for Pork, Ratites, and Injected Meats

In the 1997 FDA Food Code and in the 1998 baseline data collection, the critical limit for cooking all pork, ratites such as ostrich and emu, and injected meats was 155°F (68°C) for 15 seconds. Subsequent research showed that a lower temperature was adequate for destroying the biological hazards in pork; thus, the critical limit for cooking pork was changed in the 1999 FDA Food Code to 145°F (63°C) for 15 seconds. The critical limit for cooking ratites and injected meats remained unchanged.

In order to determine whether lowering the cooking temperature of pork had any effect on industry's ability to control this risk factor, supplemental data items were added relating to the cooking of pork and ratites. Data item 4G remained the same, but supplemental data items 17A and 17B were added to assess the effect of the modified standard for cooking pork. Data item 17A was evaluated on whether pork was cooked to 145°F instead of the previous standard of 155°F. Data item 17B is identical to data item 4G except that pork is not included in this data item. Data items 17A and 17B have been recombined into 4G(NEW) in Table 35 on page 171 to illustrate the effect of the new standard.

Table 35 shows the total IN and OUT observations for each facility type for data item 4G and the total IN and OUT observations for data item 4G(NEW) which is how the data item would have been marked if the new standard had been used. That is:

4G(NEW) Pork cooked to 145°F for 15 seconds; Ratites and injected meats cooked to 155°F for 15 seconds.

Although there were not enough observations to draw any definitive conclusions on the effect of the new standard on industry's ability to cook pork properly, the data shows that there were three instances in nursing homes in which data item 4G was Out of Compliance when data item 4G (NEW) would have been IN Compliance. Similarly, in

full service restaurants, there were two instances in which data item 4G was Out of Compliance when data item 4G (NEW) would have been In Compliance. Thus, there were cases in which a pork product was measured at a temperature higher than 145°F but less than 155°F.

Table 35

Observations Made of Pork, Ratites, and Injected Meats Cooked to 155°F (68°C) for 15 Seconds (Data Item 4G) vs. Pork Being Cooked to 145°F (63°C) for 15 Seconds and Ratites/Injected Meats Cooked to 155°F (68°C) for 15 Seconds (Data Item 4GNEW)

Facility Type	"4G" Total IN Obs. Cooking ALL to 155°F	"4G" Total OUT Obs. Cooking ALL to 155°F	Total	"4GNEW" Total IN Obs. Cooking Pork to 145°F; Ratites/Injected Meats to 155°F	"4GNEW" Total OUT Obs. Cooking Pork to 145°F; Ratites/Injected Meats to 155°F	Total
Hospitals	20	0	20	20	0	20
Nursing Homes	13	3	16	16	0	16
Elementary Schools	0	0	0	0	0	0
Fast Food Restaurants	7	0	7	7	0	7
Full Service Restaurants	22	5	27	24	3	27
Delis	5	1	6	5	1	6
Meat and Poultry	1	0	1	1	0	1
Seafood	0	0	0	0	0	0
Produce	0	0	0	0	0	0

Hot Holding PHF/TCS Food at 135°F (57°C)

In the 1997 FDA Food Code and in the 1998 baseline data collection, the critical limit for hot holding PHF/TCS Food was 140°F (59°C). This temperature was lowered to 135°F (57°C) in the Supplement to the 2001 Food Code. A supplemental data item was added for hot holding at 135°F (57°C) to better assess industry's practices and procedures related to control of holding foods hot.

As shown in Table 36, changing the hot holding to 135°F (57°C) had minimal impact on industry's control of holding PHF/TCS Food hot. None of the changes in the IN Compliance percentages were statistically significant. There were not enough observations to draw any conclusions for the meat and poultry, seafood, and produce facility types.

Table 36

Hot Holding at 140°F (Data Items 8A) vs.
Hot Holding at 135°F (Data Item 18A)

Facility Type	"8A" Total IN 140°F	"8A" Total OUT 140°F	"8A" Total 140°F	"8A" % IN 140°F	"18A" Total IN 135°F	"18A" Total OUT 135°F	"18A" Total 135°F	"18A" % IN 135°F	Difference (% IN)
Hospitals	43	37	80	53.75	50	30	80	62.50	8.75
Nursing Homes	54	22	76	71.05	59	17	76	77.63	6.58
Elementary Schools	52	26	78	66.67	58	20	78	74.36	7.69
								1	
Fast Food Restaurants	63	26	89	70.79	70	19	89	78.65	7.86
Full Service Restaurants	52	35	87	59.77	56	31	87	64.37	4.60
Delis	43	49	92	46.74	50	42	92	54.35	7.61
Meat and Poultry	0	2	2	0.00*	1	1	2	50.00*	50.00*
Seafood	0	1	1	0.00*	0	1	1	0.00*	0.00*
Produce	9	0	9	100.0*	9	0	9	100.0*	0.00*

^{*} The number of observations for these 3 facility types is too low to make comparisons

Employee Health

The employee health portion of Chapter 2 of the 2001 FDA Food Code is one of the key public health interventions for preventing foodborne illness resulting from infected food workers. Given the importance of employee health issues in preventing foodborne illness, FDA desires to gain a better understanding of industry practices and procedures related to this public health intervention. Although documentation is not specifically required to demonstrate compliance with Chapter 2 of the 2001 FDA Food Code, FDA wanted to assess the prevalence of formal, written employee health policies implemented by industry. Specifically, Specialists were instructed to determine if an establishment had a written policy for addressing the following:

- Medical questionnaire upon a conditional offer of employment
- When to exclude or restrict food employees based on illnesses or symptoms
- When to remove exclusions or restrictions
- Responsibility of food employees to report certain illnesses and symptoms to the person in charge
- Responsibility of the person in charge to report illnesses designated in the Food Code to the regulatory authority

As shown in Table 37, lack of a formal, written employee health policy was noted in all facility types. All facility types should place more effort on implementing practices, procedures, and policies that address employee health concerns.

Table 37

Written Employee Health Policies (Data Item – 19A)

Facility Type	Total IN	Total OUT	Total Obs.	Percent IN
Hospitals	42	48	90	46.67
Nursing Homes	21	72	93	22.58
Elementary Schools	19	74	93	20.43
Fast Food Restaurants	24	79	103	23.30
Full Service Restaurants	13	83	96	13.54
Delis	28	70	98	28.57
Meat and Poultry	29	70	99	29.29
Seafood	25	57	82	30.49
Produce	27	69	96	28.13

Juices and Eggs

The 2001 FDA Food Code includes provisions to address the treatment of packaged juice at the retail level. Specifically, juice packaged at the retail level must be pasteurized or otherwise treated to attain a 5-log reduction of the most pertinent microorganism or bear a warning label. Across all facility types, only seven total observations of juice treatment were noted during the 2008 data collection. As a result, the sample size for these data items is too small to draw any conclusions.

In addition, the 2001 FDA Food Code includes provisions to address the cold holding and cooling of raw shell eggs. Specifically, FDA was looking at industry's control of cold holding raw shell eggs at an ambient temperature of 45°F (7°C) and the cooling of raw shell eggs by being placed under refrigeration at an ambient temperature of 45°F (7°C) upon receipt.

As shown in Table 38, the bolded facility types, namely hospitals, nursing homes, elementary schools, fast food restaurants, and full service restaurants, appear to have control over the proper cold holding of raw shell eggs (% IN Compliance range: 87.32 – 100%). There were not enough observations to make any conclusions about cold holding of raw shell eggs for the other facility types. For the cooling of raw shell eggs, there were not enough observations to draw any conclusions for any of the facility types.

Table 38

Cold Holding of Eggs (Data Item – 22A)

Facility Type	Total IN	Total OUT	Total Obs.	Percent IN
Hospitals	56	0	56	100.00
Nursing Homes	54	1	55	98.18
Elementary Schools	21	1	22	95.45
Fast Food Restaurants	26	0	26	100.00
Full Service Restaurants	62	9	71	87.32
Delis	16	0	16	100.00
Meat and Poultry	8	0	8	100.00
Seafood	0	0	0	
Produce	19	3	22	86.36

Highly Susceptible Populations

Lastly, FDA wanted to assess the compliance status of institutions with regard to three specific requirements in the 2001 FDA Food Code related to the prevention of foodborne illness in highly susceptible populations:

- Prohibiting the service of juice bearing a warning label (untreated or unpasteurized juice) (Data Item – 23A)
- Use of pasteurized eggs (no use of raw shell eggs, with exceptions, as ingredients in certain foods or when combined and cooked) (Data Item – 23B)
- No raw or undercooked animal foods or sprouts served (Data Item 23C)

As shown in Table 39, there were no Out of Compliance observations in institutional facility types for data item 23A.

Table 39

Prepackaged Juice/Beverage Containing Juice with Warning Label
(Data Item – 23A)

Facility Type	Total IN	Total OUT	Total Obs.	Percent IN
Hospitals	82	0	82	100.00
Nursing Homes	87	0	87	100.00
Elementary Schools	86	0	86	100.00

NOTE: The three facility types listed in Table 39 meet the Food Code definition of establishments that serve a Highly Susceptible Population

Hospitals, nursing homes, and elementary schools appear to have processes or procedures in place for data items 23B (Table 40) and 23C (Table 41) related to the use of pasteurized eggs and no raw or undercooked animal foods or sprouts being served, respectively.

Table 40

Pasteurized Eggs or Eggs Substituted for Raw Shell Eggs (Data Item – 23B)

Facility Type	Total IN	Total OUT	Total Obs.	Percent IN
Hospitals	77	5	82	93.90
Nursing Homes	76	7	83	91.57
Elementary Schools	50	1	51	98.04

NOTE: The three facility types listed in Table 40 meet the Food Code definition of establishments that serve a Highly Susceptible Population

Table 41

Raw or Partially Cooked Animal Food and Raw Seed Sprouts not Served (Data Item – 23C)

Facility Type	Total IN	Total OUT	Total Obs.	Percent IN
Hospitals	71	5	76	93.42
Nursing Homes	74	6	80	92.50
Elementary Schools	71	0	71	100.00

NOTE: The three facility types listed in Table 41 meet the Food Code definition of establishments that serve a Highly Susceptible Population

APPENDICES

APPENDIX A – HOSPITALS

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA			
Food From Unsafe Sources								
1A	All food from Regulated Food Processing Plants/No Home prepared/canned foods	89	1	0	0			
1B	All shellfish from NSSP listed sources. No recreationally caught shellfish received or sold	7	0	0	83			
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	1	0	0	89			
2A	Food received at proper temperatures/protected from contamination during transportation and receiving/food is safe, unadulterated	85	5	0	0			
3A	Shellstock tags/labels retained for 90 days from the date the container is emptied As required, written documentation of parasite destruction maintained	1	1	1	87			
3B	for 90 days for fish products CCP monitoring records maintained in accordance with HACCP plan	1	1	0	88			
3C	when required	0	1	0	89			
	Inadequate Cooking							
4A	Raw shell eggs broken for immediate service cooked to 145 °F (63 °C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to155°F (68°C) for 15 seconds	6	1	42	41			
4B	Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for 15 seconds	40	0	46	4			
4C	Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specified and according to oven parameters per Chart	6	0	68	16			
4D	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds	46	0	40	4			
4E	Wild game animals cooked to 165°F (74°C) for 15 seconds	0	0	1	89			
4F	Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165°F (74°C). Food is allowed to stand covered for 2 minutes after cooking	0	0	0	90			
4G	Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds.	20	0	63	7			
4H	All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds PHF/TCS Food that is cooked and cooled on premises is rapidly	33	0	54	3			
5A 5B	reheated to 165°F (74°C) for 15 seconds for hot holding	25	0	54 21	10 69			
5C	Food reheated in a microwave is heated to 165 °F (74 °C) or higher Commercially processed ready-to-eat food, reheated to 140°F (60°C) or above for hot holding	39	3	38	10			
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	2	0	44	44			

APPENDIX A - HOSPITALS

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
#	Improper Holding/Time & Temperature	IIN	001	NO	NA
	· · · · · · · · · · · · · · · · · · ·		I		
6A	Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6 hours	13	19	53	5
6B	PHF/TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours	14	11	61	4
6C	Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours	9	0	77	4
7A	PHF/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.	40	50	0	0
8A	PHF/TCS Food is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.	43	37	7	3
8B	Roasts are held at a temperature of 130°F (54°C) or above	6	0	50	34
9A	Ready-to-eat PHF/TCS Food held for more than 24 hours is date marked as required (prepared on-site)	67	20	2	1
9B	Discard RTE PHF/TCS Food and/or opened commercial container exceeding 7 days at ≤ 41°F (5°C) or 4 days at ≤ 45°F (7°C)	61	10	17	2
9C	Opened Commercial container of prepared ready-to-eat PHF/TCS Food is date marked as required	55	28	6	1
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	0	0	3	87
	Contaminated Equipment/Protection from Contam	inat	ion		
10A	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food	61	26	0	3
10A	Raw animal foods are separated from each other during storage, preparation, holding, and display	79	7	1	3
10C	Food is protected from environmental contamination – critical Items	77	13	0	0
10D	After being served or sold to a consumer, food is not re-served	90	0	0	0
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	58	32	0	0

APPENDIX A - HOSPITALS

DATA	DATA COMMINATO (page 0 of 4)				
ITEM	DATA ITEM	#	#	#	#
#		IN	OUT	NO	NA
	Poor Personal Hygiene				
12A	Hands are clean and properly washed when and as required	58	32	0	0
	Food employees eat, drink, and use tobacco only in				
	designated areas/do not use a utensil more than once to taste food that is sold or served / do not handle or care for				
	animals present. Food employees experiencing persistent				
	sneezing, coughing, or runny nose do not work with exposed				
	food, clean equipment, utensils, linens, unwrapped single-				
13A	service or single-use articles	78	12	0	0
14A	Employees do not contact exposed, ready-to-eat food with their bare hands.	81	8	1	0
1-7/1	Handwash facilities conveniently located and accessible for				
15A	Employees	69	21	0	0
4.5-	Handwash facilities supplied with hand cleanser/sanitary				
15B	towels/hand drying devices	86	4	0	0
	Other/Chemical				
464	If used, only approved food or color additives. Sulfites are not	_		0	0.4
16A	applied to fresh fruits and vegetables intended for raw consumption Poisonous or toxic materials, chemicals, lubricants, pesticides,	5	1	0	84
	medicines, first aid supplies, and other personal care items are				
16B	properly identified, stored and used	77	13	0	0
16C	Poisonous or toxic materials held for retail sale are properly stored	0	0	0	90
	Supplemental Items – New Areas of Study				
17A	Pork is cooked to 145°F (63°C) or above for 15 seconds	20	0	60	10
450	Ratites and injected meats are cooked to 155°F (68°C) for 15	_		00	40
17B	seconds	3	0	39	48
	PHF/TCS Food is maintained at 135°F (57°C) or above, except during preparation, cooking, or cooling or when time is used as a				
18A	public health control	50	30	7	3
	Facility has a written policy that is consistent with 2-201 of the <i>Food</i>				
	Code for excluding and restricting employees on the basis of their				
	health and activities as they relate to diseases that are transmissible through food. Written policy includes a statement regarding				
	employee responsibility to notify management of symptoms and				
19A	illnesses identified in the <i>Food Code</i> .	42	48	0	0
	When packaged in a food establishment, juice is treated under a				
20.4	HACCP Plan to reduce pathogens or be labeled as specified in the Food Code	1	0	0	89
20A	After receiving, raw shell eggs are immediately placed under	1	U	U	09
	refrigeration that maintains ambient air temperature of 45°F (7°C) or				
21A	less	4	0	53	33
00.1	After receipt, raw shell eggs are stored in refrigerated equipment that				6.0
22A	maintains ambient air temperature of 45°F (7°C) or less	56	0	1	33

APPENDIX A – HOSPITALS

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	82	0	0	8
23B	Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls <i>Salmonella Enteritidis</i>	77	5	4	4
23C	Raw or partially cooked animal food and raw seed sprouts not served	71	5	0	14

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA		
Food From Unsafe Sources							
1A	All food from Regulated Food Processing Plants/No Home prepared/canned foods	92	1	0	0		
1B	All shellfish from NSSP listed sources. No recreationally caught shellfish received or sold	4	0	0	89		
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	1	0	0	92		
2A	Food received at proper temperatures/protected from contamination during transportation and receiving/food is safe, unadulterated	90	3	0	0		
3A	Shellstock tags/labels retained for 90 days from the date the container is emptied	1	0	0	92		
3B	As required, written documentation of parasite destruction maintained for 90 days for fish products	0	0	0	93		
3C	CCP monitoring records maintained in accordance with HACCP plan when required	0	0	0	93		
	Inadequate Cooking						
4A	Raw shell eggs broken for immediate service 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	6	1	46	40		
4B	Comminuted Fish, Meats, Game animals cooked to 155 °F (68°C) for 15 seconds	23	3	66	1		
4C	Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specified and according to oven parameters per Chart	7	0	68	18		
4D	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds	19	2	68	4		
4E	Wild game animals cooked to 165°F (74°C) for 15 seconds	0	0	0	93		
4F	Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165 °F (74°C). Food is allowed to stand covered for 2 minutes after cooking	0	0	1	92		
4G	Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds.	13	3	68	9		
4H	All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds PHF/TCS Food that is cooked and cooled on premises is rapidly	27	1	65	0		
5A	reheated to 165°F (74°C) for 15 seconds for hot holding	17	1	69	6		
5B	Food reheated in a microwave is heated to 165°F (74°C) or higher	1	1	24	67		
5C	Commercially processed ready-to-eat food, reheated to 140°F (60°C) or above for hot holding	33	4	52	4		
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	4	0	50	39		

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
#	Improper Holding/Time & Temperature	IIN	001	NO	NA
	·				
6A	Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6 hours	6	23	59	5
6B	PHF/TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours	7	12	69	5
6C	Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours	10	1	82	0
7A	PHF/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.	72	21	0	0
8 A	PHF/TCS Food is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.	54	22	17	0
8B	Roasts are held at a temperature of 130°F (54°C) or above	3	1	54	35
9A	Ready-to-eat PHF/TCS Food held for more than 24 hours is date marked as required (prepared on-site)	69	19	5	0
9B	Discard RTE PHF/TCS Food and/or opened commercial container exceeding 7 days at ≤ 41°F (5°C) or 4 days at ≤ 45°F (7°C)	69	12	12	0
9C	Opened Commercial container of prepared ready-to-eat PHF/TCS Food is date marked as required	52	30	11	0
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	0	0	2	91
	Contaminated Equipment/Protection from Contam	inati	ion		
10A	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food	64	28	0	1
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	79	9	3	2
10C	Food is protected from environmental contamination – critical Items	82	11	0	0
10D	After being served or sold to a consumer, food is not re-served	93	0	0	0
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	64	29	0	0

DATA					
ITEM	DATA ITEM	#	#	#	#
#		IN	OUT	NO	NA
	Poor Personal Hygiene				
12A	Hands are clean and properly washed when and as required	59	31	3	0
	Food Employees eat, drink, and use tobacco only in designated				
	areas/do not use a utensil more than once to taste food that is sold or				
	served / do not handle or care for animals present. Food employees experiencing persistent sneezing, coughing, or runny nose do not				
	work with exposed food, clean equipment, utensils, linens,				
13A	unwrapped single-service or single-use articles	80	11	2	0
	Employees do not contact exposed, ready-to-eat food with their bare				
14A	hands.	77	11	5	0
	Handwash facilities conveniently located and accessible for				
15A	Employees	81	12	0	0
4=5	Handwash facilities supplied with hand cleanser/sanitary	0.5		_	
15B	towels/hand drying devices	85	8	0	0
	Other/Chemical				
404	If used, only approved food or color additives. Sulfites are not	_		0	00
16A	applied to fresh fruits and vegetables intended for raw consumption Poisonous or toxic materials, chemicals, lubricants, pesticides,	3	0	0	90
	medicines, first aid supplies, and other personal care items are				
16B	properly identified, stored and used	81	12	0	0
16C	Poisonous or toxic materials held for retail sale are properly stored	0	0	0	93
	Supplemental Items – New Areas of Study				
17A	Pork is cooked to 145°F (63°C) or above for 15 seconds	14	0	70	9
	Ratites and injected meats are cooked to 155°F (68°C) for 15				
17B	seconds	3	0	37	53
	PHF/TCS Food is maintained at 135°F (57°C) or above, except				
18A	during preparation, cooking, or cooling or when time is used as a	59	17	17	0
IOA	public health control Facility has a written policy that is consistent with 2-201 of the Food	59	17	17	U
	Code for excluding and restricting employees on the basis of their				
	health and activities as they relate to diseases that are transmissible				
	through food. Written policy includes a statement regarding				
	employee responsibility to notify management of symptoms and				
19A	illnesses identified in the Food Code.	21	72	0	0
	When packaged in a food establishment, juice is treated under a				
20.4	HACCP Plan to reduce pathogens or be labeled as specified in the	^		_	00
20A	Food Code After receiving, raw shell eggs are immediately placed under	0	0	0	93
	refrigeration that maintains ambient air temperature of 45°F (7°C) or				
21A	less	5	1	53	34
	After receipt, raw shell eggs are stored in refrigerated equipment that				-
22A	maintains ambient air temperature of 45°F (7°C) or less	54	1	3	35

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	87	0	0	6
23B	Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls Salmonella Enteritidis.	76	7	6	4
23C	Raw or partially cooked animal food and raw seed sprouts not served	74	6	1	12

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA		
Food From Unsafe Sources							
1A	All food from Regulated Food Processing Plants/No Home prepared/canned foods	93	0	0	0		
1B	All shellfish from NSSP listed sources. No recreationally caught shellfish received or sold Game, wild mushrooms harvested with approval of Regulatory	1	0	0	92		
1C	Authority Food received at proper temperatures/protected from contamination	0	0	0	93		
2A	during transportation and receiving/food is safe, unadulterated Shellstock tags/labels retained for 90 days from the date the	86	7	0	0		
3A	container is emptied As required, written documentation of parasite destruction maintained	0	0	0	93		
3B	for 90 days for fish products CCP monitoring records maintained in accordance with HACCP plan	0	0	0	93		
3C	when required	0	0	0	93		
	Inadequate Cooking Raw shell eggs broken for immediate service cooked to 145°F (63°C)						
4A	for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to 155°F (68°C) for 15 seconds	0	0	14	79		
4B	Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for 15 seconds	1	0	24	68		
4C	Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specified and according to oven parameters per Chart	0	0	4	89		
4D	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds	3	0	34	56		
4E	Wild game animals cooked to 165°F (74°C) for 15 seconds	0	0	0	93		
4F	Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165°F (74°C). Food is allowed to stand covered for 2 minutes after cooking	0	0	0	93		
4G	Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds.	0	0	6	87		
4H	All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds PHF/TCS Food that is cooked and cooled on premises is rapidly	2	0	16	75		
5A 5B	reheated to 165°F (74°C) for 15 seconds for hot holding Food reheated in a microwave is heated to 165°F (74°C) or higher	8	2	45 6	38 87		
5C	Commercially processed ready-to-eat food, reheated to 140°F (60°C) or above for hot holding	53	7	25	8		
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	0	0	3	90		

DATA	DATA GOMMANT (page 2 of 4)				
ITEM	DATA ITEM	#	#	#	#
#		IN	OUT	NO	NA
	Improper Holding/Time & Temperature				
	Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F (21°C)				
	within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6				
6A	hours	2	3	59	29
6B	PHF/TCS Food (prepared from ingredients at ambient temperature)	9	7	59	18
0D	is cooled to 41°F (5°C) or below within 4 hours Foods received at a temperature according to Law are cooled to 41°F	9		59	10
6C	(5°C) within 4 hours	11	0	66	16
	PHF/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				
7A	control.	66	27	0	0
	PHF/TCS Food is maintained at 140°F (60°C) or above, except				
8A	during preparation, cooking, or cooling or when time is used as a public health control.	52	26	13	2
8B	Roasts are held at a temperature of 130°F (54°C) or above	0	0	2	91
	Ready-to-eat PHF/TCS Food held for more than 24 hours is date				
9A	marked as required (prepared on-site)	41	8	15	29
25	Discard RTE PHF/TCS Food and/or opened commercial container	40		00	00
9B	exceeding 7 days at \leq 41°F (5°C) or 4 days at \leq 45°F (°C)	42	8	20	23
9C	Opened Commercial container of prepared ready-to-eat PHF/TCS Food is date marked as required	37	20	7	29
	When time only is used as a public health control, food is cooked and			•	
9D	served within 4 hours as required	4	1	1	87
	Contaminated Equipment/Protection from Contam	inat	ion		
	Food is protected from cross contamination by separating raw animal				
400	foods from raw ready-to-eat food and by separating raw animal foods	00	_		
10A	from cooked ready-to-eat food Raw animal foods are separated from each other during storage,	29	7	6	51
10B	preparation, holding, and display	21	3	5	64
10C	Food is protected from environmental contamination – critical items	83	10	0	0
10D	After being served or sold to a consumer, food is not re-served	91	2	0	0
	Food-contact surfaces and utensils are clean to sight and touch and				
11A	sanitized before use	65	28	0	0

Poor Personal Hygiene 12A Hands are clean and properly washed when and as required Food Employees eat, drink, and use tobacco only in designated areas/do not use a utensil more than once to taste food that is sold or served / do not handle or care for animals present. 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 Employees do not contact exposed, ready-to-eat food with their bare hands. Handwash facilities conveniently located and accessible for Employees Employees Handwash facilities supplied with hand cleanser/sanitary towels/hand drying devices Other/Chemical If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw Consumption Other/Chemical If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw Consumption Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are properly identified, stored and used 16C Poisonous or toxic materials held for retail sale are properly stored Supplemental Items – New Areas of Study 17A Pork is cooked to 145°F (63°C) or above for 15 seconds PHF/TCS Food is maintained at 135°F (57°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control Facility has a written policy that is consistent with 2-201 of the Food Code for excluding and restricting employees on the basis of their health and activities as they relate to diseases that are transmissible through food. Written policy includes a statement regarding employee responsibility to notify management of symptoms and illnesses identified in the Food Code After receiving, raw shell eggs are immediately placed under refrigeration that maintains ambient air temperature of 45°F (7°C) or 1 1 23	DATA	DATA COMMINATO (page 5 of 4)								
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Poor Personal Hygiene 12A Hands are clean and properly washed when and as required Food Employees eat, drink, and use tobacco only in designated areas/do not use a utensil more than once to taste food that is sold or served / do not handle or care for animals present. 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 Employees do not contact exposed, ready-to-eat food with their bare hands. Employees do not contact exposed, ready-to-eat food with their bare hands. Handwash facilities conveniently located and accessible for Employees Handwash facilities supplied with hand cleanser/sanitary towels/hand drying devices Other/Chemical If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw Consumption Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are need file. Prosonous or toxic materials held for retail sale are properly stored Supplemental Items – New Areas of Study 17A Pork is cooked to 145°F (63°C) or above for 15 seconds Ratities and injected meats are cooked to 155°F (68°C) for 15 seconds PHF/TCS Food is maintained at 135°F (57°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control Facility has a written policy that is consistent with 2-201 of the Food Code for excluding and restricting employees on the basis of their health and activities as they relate to diseases that are transmissible through food. Written policy includes a statement regarding employee responsibility to notify management of symptoms and illnesses identified in the Food Code When packaged in a food establishment, juice is treated under a HACCP Plan to reduce pathogens or be labeled as specified in the Food Code labeled as specified in the Food Code labeled as specified in the Food Code labeled as spe		DATATIEM				NA				
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16B properly identified, stored and used 16C Poisonous or toxic materials held for retail sale are properly stored 0 0 0 0										
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21A less 1 1 23										
	21 /		1	1	23	68				
■ Atter receipt if aw shell edgs are stored in retriderated equipment that ■	ZIA	After receipt, raw shell eggs are stored in refrigerated equipment that	<u> </u>	<u>'</u>	20	00				
22A maintains ambient air temperature of 45°F (7°C) or less 21 1 2	22A		21	1	2	69				

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	86	0	0	7
23B	Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls <i>Salmonella Enteritidis</i> .	50	1	4	38
23C	Raw or partially cooked animal food and raw seed sprouts not served	71	0	0	22

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA					
Food From Unsafe Sources										
4.0	All food from Regulated Food Processing Plants/No Home	100	3	0	0					
1A	prepared/canned foods All shellfish from NSSP listed sources. No recreationally caught	100	<u> </u>	0	0					
1B	shellfish received or sold	2	0	0	101					
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	0	0	0	103					
1	Food received at proper temperatures/protected from contamination									
2A	during transportation and receiving/food is safe, unadulterated	102	1	0	0					
3A	Shellstock tags/labels retained for 90 days from the date the container is emptied	0	0	0	103					
1	As required, written documentation of parasite destruction									
3B	maintained for 90 days for fish products CCP monitoring records maintained in accordance with HACCP	0	0	0	103					
3C	plan when required	0	1	0	102					
	Inadequate Cooking									
	Raw shell eggs broken for immediate service cooked to 145°F									
4A	(63°C) for 15 seconds. Raw shell eggs broken but not prepared for	6	0	22	75					
774	immediate service cooked to 155°F (68°C) for 15 seconds Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for				70					
4B	15 seconds	43	4	10	46					
	Roasts, including formed roasts, are cooked to 130°F (5 °C) for 112 minutes or as Chart specified and according to oven parameters									
4C	per Chart	2	0	7	94					
	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,									
4D	stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (7 °C) for 15 seconds	43	3	19	38					
4E	Wild game animals cooked to 165°F (74°C) for 15 seconds	0	0	0	103					
	Raw animal foods cooked in microwave are rotated, stirred,									
4F	covered, and heated to 165°F (74°C). Food is allowed to stand covered for 2 minutes after cooking	2	1	2	98					
	Pork, ratites, injected meats are cooked to 155°F (68°C) for 15		-							
4G	seconds.	7	0	18	78					
4H	All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds PHF/TCS Food that is cooked and cooled on premises is rapidly	20	1	30	52					
5A	reheated to 165°F (74°C) for 15 seconds for hot holding	8	2	29	64					
5B	Food reheated in a microwave is heated to 165°F (74°C) or higher	4	1	22	76					
50	Commercially processed ready-to-eat food, reheated to 140°F	20	4	45	20					
5C	(60°C) or above for hot holding Remaining unsliced portions of roasts are reheated for hot	28	1	45	29					
5D	holding using minimum oven parameters	0	0	3	100					

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Improper Holding/Time & Temperature				
6A	Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6 hours	7	11	39	46
6B	PHF/TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours	6	5	41	51
6C	Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours	1	0	64	38
7 A	PHF/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.	33	70	0	0
8 A	PHF/TCS Food is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.	63	26	4	10
8B	Roasts are held at a temperature of 130°F (54°C) or above	4	1	5	93
9A	Ready-to-eat PHF/TCS Food held for more than 24 hours is date marked as required (prepared on-site)	47	19	4	33
9B	Discard RTE PHF/TCS Food and/or opened commercial container exceeding 7 days at \leq 41°F (5°C) or 4 days at \leq 45°F (7°C)	54	7	24	18
9C	Opened Commercial container of prepared ready-to-eat PHF/TCS Food is date marked as required	42	23	13	25
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	15	6	0	82
	Contaminated Equipment/Protection from Contan	ninat	ion		
10A	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food	69	10	0	24
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	61	6	0	36
10C 10D	Food is protected from environmental contamination – critical items After being served or sold to a consumer, food is not re-served	83 103	20 0	0	0
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	60	43	0	0

Food area serv expe work 13A unw Emp 14A hand Hand 15A emp	dwash facilities conveniently located and accessible for loyees dwash facilities supplied with hand cleanser/sanitary	# IN 60 79 73 84	38 23 26	5	# NA 0
12A Han Food area serv expe work 13A unw 14A hand Han 15A emp	ds are clean and properly washed when and as required d Employees eat, drink, and use tobacco only in designated as/do not use a utensil more than once to taste food that is sold or red / do not handle or care for animals present. Food employees eriencing persistent sneezing, coughing, or runny nose do not with exposed food, clean equipment, utensils, linens, rapped single-service or single-use articles ployees do not contact exposed, ready-to-eat food with their bare ds. dwash facilities conveniently located and accessible for ployees dwash facilities supplied with hand cleanser/sanitary	79 73	38	5	0
Food area serv expe work 13A unw 14A hand Hand 15A emp	ds are clean and properly washed when and as required d Employees eat, drink, and use tobacco only in designated as/do not use a utensil more than once to taste food that is sold or red / do not handle or care for animals present. Food employees eriencing persistent sneezing, coughing, or runny nose do not with exposed food, clean equipment, utensils, linens, rapped single-service or single-use articles ployees do not contact exposed, ready-to-eat food with their bare ds. dwash facilities conveniently located and accessible for ployees dwash facilities supplied with hand cleanser/sanitary	79 73	23	1	
Food area serv expe work 13A unw 14A hand Hand 15A emp	d Employees eat, drink, and use tobacco only in designated as/do not use a utensil more than once to taste food that is sold or red / do not handle or care for animals present. Food employees eriencing persistent sneezing, coughing, or runny nose do not with exposed food, clean equipment, utensils, linens, rapped single-service or single-use articles oloyees do not contact exposed, ready-to-eat food with their bare ds. dwash facilities conveniently located and accessible for oloyees dwash facilities supplied with hand cleanser/sanitary	73			0
servex expenses work 13A unw Employment 14A hand 15A employment 15A	red / do not handle or care for animals present. Food employees eriencing persistent sneezing, coughing, or runny nose do not with exposed food, clean equipment, utensils, linens, rapped single-service or single-use articles ployees do not contact exposed, ready-to-eat food with their bare ds. dwash facilities conveniently located and accessible for ployees dwash facilities supplied with hand cleanser/sanitary	73			0
experiments work work 13A unw Emp 14A hand 15A emp	eriencing persistent sneezing, coughing, or runny nose do not k with exposed food, clean equipment, utensils, linens, rapped single-service or single-use articles ployees do not contact exposed, ready-to-eat food with their bare ds. dwash facilities conveniently located and accessible for ployees dwash facilities supplied with hand cleanser/sanitary	73			0
13A work 13A unw Emp 14A hand Hand 15A emp	with exposed food, clean equipment, utensils, linens, rapped single-service or single-use articles bloyees do not contact exposed, ready-to-eat food with their bare ds. dwash facilities conveniently located and accessible for bloyees dwash facilities supplied with hand cleanser/sanitary	73			0
13A unw Emp 14A hand Hand 15A emp	rapped single-service or single-use articles bloyees do not contact exposed, ready-to-eat food with their bare ds. dwash facilities conveniently located and accessible for bloyees dwash facilities supplied with hand cleanser/sanitary	73			0
14A hand Hand 15A emp	oloyees do not contact exposed, ready-to-eat food with their bare ds. dwash facilities conveniently located and accessible for oloyees dwash facilities supplied with hand cleanser/sanitary	73	26		
Hander 15A emp	dwash facilities conveniently located and accessible for loyees dwash facilities supplied with hand cleanser/sanitary		26		ı
15A emp	dwash facilities supplied with hand cleanser/sanitary	84		4	0
	dwash facilities supplied with hand cleanser/sanitary	84	40	_	
Han		<u> </u>	19	0	0
	els/hand drying devices	87	16	0	0
102 1011	Other/Chemical	σ.	. •	J	<u> </u>
If us	ed, only approved food or color additives. Sulfites are not				
	ied to fresh fruits and vegetables intended for raw consumption	1	1	0	101
	conous or toxic materials, chemicals, lubricants, pesticides,				
	licines, first aid supplies, and other personal care items are	71	20	0	^
	perly identified, stored and used sonous or toxic materials held for retail sale are properly stored	0	32 0	0	103
100	Supplemental Items – New Areas of Study	Ü	Ū	Ū	100
17A Pork	is cooked to 145°F (63°C) or above for 15 seconds	6	0	18	79
	tes and injected meats are cooked to 155°F (68°C) for 15				
17B seco		1	0	9	93
	T/TCS Food is maintained at 135°F (57°C) or above, except				
	ng preparation, cooking, or cooling or when time is used as a ic health control	70	19	4	10
	lity has a written policy that is consistent with 2-201 of the <i>Food</i>	70	13		10
	e for excluding and restricting employees on the basis of their				
heal	th and activities as they relate to diseases that are transmissible				
	ugh food. Written policy includes a statement regarding				
	social dentified in the Food Code	24	79	0	_
	sses identified in the <i>Food Code</i> . en packaged in a food establishment, juice is treated under a	∠4	79	U	0
	CCP Plan to reduce pathogens or be labeled as specified in the				
20A Food	d Code	0	1	0	102
	r receiving, raw shell eggs are immediately placed under				
	geration that maintains ambient air temperature of 45°F (7°C) or	_		0.7	70
21A less		0	0	27	76
	r receipt, raw shell eggs are stored in refrigerated equipment that nains ambient air temperature of 45°F (7°C) or less	26	0	1	76

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.)				
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	103
23B	Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls Salmonella Enteritidis	0	0	0	103
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	103

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA					
	Food From Unsafe Sources									
4.0	All food from Regulated Food Processing Plants/No Home	93	3	0	0					
1A	prepared/canned foods All shellfish from NSSP listed sources. No recreationally caught	93	3	U	U					
1B	shellfish received or sold	20	2	0	74					
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	4	1	1	90					
2A	Food received at proper temperatures/protected from contamination during transportation and receiving/food is safe, unadulterated	88	8	0	0					
3A	Shellstock tags/labels retained for 90 days from the date the container is emptied	7	7	0	82					
3B	As required, written documentation of parasite destruction maintained for 90 days for fish products	1	4	0	91					
3C	CCP monitoring records maintained in accordance with HACCP plan when required	0	4	0	92					
	Inadequate Cooking									
	Raw shell eggs broken for immediate service cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for									
4A	immediate service cooked to 155°F (68°C) for 15 seconds	16	2	45	33					
4B	Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for 15 seconds	43	2	39	12					
4C	Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specified and according to oven parameters per Chart	2	2	25	67					
4D	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds	39	5	49	3					
4E	Wild game animals cooked to 165°F (74°C) for 15 seconds	0	0	2	94					
4F	Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165°F (74°C). Food is allowed to stand covered for 2 minutes after cooking	1	0	1	94					
4G	Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds.	22	5	44	25					
4H	All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds PHF/TCS Food that is cooked and cooled on premises is rapidly	34	5	51	6					
5A	reheated to 165°F (74°C) for 15 seconds for hot holding	13	9	62	12					
5B	Food reheated in a microwave is heated to 165°F (74°C) or higher	2	2	20	72					
5C	Commercially processed ready-to-eat food, reheated to 140°F (60°C) or above for hot holding	19	2	48	27					
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	1	1	20	74					

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA			
"	Improper Holding/Time & Temperature							
	Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F (21°C)							
6A	within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6 hours	9	33	52	2			
6B	PHF/TCS Food (prepared from ingredients at ambient temperature)	10	6	65	15			
06	is cooled to 41°F (5°C) or below within 4 hours Foods received at a temperature according to Law are cooled to 41°F	10	0	03	13			
6C	(5°C) within 4 hours	1	0	84	11			
7A	PHF/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.	27	69	0	0			
8A	PHF/TCS Food is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.	52	35	6	3			
8B	Roasts are held at a temperature of 130°F (54°C) or above	4	2	20	70			
9A	Ready-to-eat PHF/TCS Food held for more than 24 hours is date marked as required (prepared on-site)	39	53	2	2			
3A	Discard RTE PHF/TCS Food and/or opened commercial container	39	- 55					
9B	exceeding 7 days at ≤ 41°F (5°C) or 4 days at ≤ 45°F (°C)	38	18	38	2			
9C	Opened Commercial container of prepared ready-to-eat PHF/TCS Food is date marked as required	33	40	12	11			
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	3	5	1	87			
	Contaminated Equipment/Protection from Contam	inat	ion					
10A	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food	53	40	1	2			
	Raw animal foods are separated from each other during storage,							
10B	preparation, holding, and display	65	25	3	3			
10C 10D	Food is protected from environmental contamination – critical items After being served or sold to a consumer, food is not re-served	58 95	38	0 0	0			
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	35	61	0	0			

DATA ITEM	DATA ITEM	#	#	#	#			
#		IN	OUT	NO	NA			
	Poor Personal Hygiene							
12A	Hands are clean and properly washed when and as required	23	72	1	0			
	Food Employees eat, drink, and use tobacco only in designated							
	areas/do not use a utensil more than once to taste food that is sold or							
	served / do not handle or care for animals present. Food employees experiencing persistent sneezing, coughing, or runny nose do not							
	work with exposed food, clean equipment, utensils, linens,							
13A	unwrapped single-service or single-use articles	72	23	1	0			
	Employees do not contact exposed, ready-to-eat food with their bare							
14A	hands.	51	44	1	0			
15A	Handwash facilities conveniently located and accessible for employees	68	28	0	0			
	Handwash facilities supplied with hand cleanser/sanitary							
15B	towels/hand drying devices	68	28	0	0			
	Other/Chemical							
	If used, only approved food or color additives. Sulfites are not							
16A	applied to fresh fruits and vegetables intended for raw consumption	7	0	0	89			
	Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are							
16B	properly identified, stored and used	70	26	0	0			
16C	Poisonous or toxic materials held for retail sale are properly stored	0	0	0	96			
	Supplemental Items – New Areas of Study							
17A	Pork is cooked to 145°F (63°C) or above for 15 seconds	17	0	52	27			
	Ratites and injected meats are cooked to 155°F (68°C) for 15							
17B	seconds	11	3	27	55			
	PHF/TCS Food is maintained at 135°F (57°C) or above, except							
18A	during preparation, cooking, or cooling or when time is used as a	56	31	6	3			
TOA	public health control Facility has a written policy that is consistent with 2-201 of the Food	50	31	0	3			
	Code for excluding and restricting employees on the basis of their							
	health and activities as they relate to diseases that are transmissible							
	through food. Written policy includes a statement regarding							
	employee responsibility to notify management of symptoms and							
19A	illnesses identified in the Food Code.	13	83	0	0			
	When packaged in a food establishment, juice is treated under a							
20A	HACCP Plan to reduce pathogens or be labeled as specified in the Food Code	0	0	0	96			
ZUA	After receiving, raw shell eggs are immediately placed under	U	J	U	30			
	refrigeration that maintains ambient air temperature of 45°F (7°C) or							
21A	less	2	0	68	26			
	After receipt, raw shell eggs are stored in refrigerated equipment that							
22A	maintains ambient air temperature of 45°F (7°C) or less	62	9	1	24			

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.)				
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	96
23B	Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls <i>Salmonella Enteritidis</i>	0	0	0	96
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	96

DATA ITEM	DATA ITEM	#	#	#	#					
#	DATATILM	IN	OUT		NA					
Food From Unsafe Sources										
	All food from Regulated Food Processing Plants/No Home									
1A	prepared/canned foods	98	0	0	0					
1B	All shellfish from NSSP listed sources. No recreationally caught shellfish received or sold	5	0	0	93					
	Game, wild mushrooms harvested with approval of Regulatory				- 00					
1C	Authority	1	0	2	95					
	Food received at proper temperatures/protected from contamination	0.5			_					
2A	during transportation and receiving/food is safe, unadulterated	95	3	0	0					
3A	Shellstock tags/labels retained for 90 days from the date the container is emptied	2	2	0	94					
	As required, written documentation of parasite destruction maintained	_			_ · ·					
3B	for 90 days for fish products	0	1	0	97					
	CCP monitoring records maintained in accordance with HACCP plan									
3C	when required	0	3	0	95					
	Inadequate Cooking				1					
	Raw shell eggs broken for immediate service cooked to 145°F (63°C)									
4A	for 15 seconds. Raw shell eggs broken but not prepared for	2	0	18	78					
7/	immediate service cooked to 155°F (68°C) for 15 seconds Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for		-	10	- 70					
4B	15 seconds	8	0	29	61					
	Roasts, including formed roasts, are cooked to 130°F (54°C) for 112									
4C	minutes or as Chart specified and according to oven parameters per	2	_	40	00					
46	Chart Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,	3	0	13	82					
	stuffed ratites, or stuffing containing fish, meat, poultry or ratites									
4D	cooked to 165°F (74°C) for 15 seconds	60	4	32	2					
4E	Wild game animals cooked to 165°F (74°C) for 15 seconds	0	0	0	98					
	Raw animal foods cooked in microwave are rotated, stirred, covered,									
₄₋	and heated to 165°F (74°C). Food is allowed to stand covered for 2	_	_	_						
4F	minutes after cooking	0	1	0	97					
4G	Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds.	5	1	32	60					
4H	All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds	9	1	40	48					
	PHF/TCS Food that is cooked and cooled on premises is rapidly									
5A	reheated to 165°F (74°C) for 15 seconds for hot holding	4	1	36	57					
5B	Food reheated in a microwave is heated to 165°F (74°C) or higher	2	1	17	78					
	Commercially processed ready-to-eat food, reheated to 140°F (60°C)									
5C	or above for hot holding	22	3	48	25					
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	0	0	10	88					

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA				
	Improper Holding/Time & Temperature								
6A	Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6 hours	16	14	52	16				
6B	PHF/TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours	11	9	54	24				
6C	Foods received at a temperature according to Law are cooled to 41°F (5 C) within 4 hours	3	0	48	47				
7A	PHF/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.	39	59	0	0				
8 A	PHF/TCS Food is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.	43	49	2	4				
8B	Roasts are held at a temperature of 130°F (54°C) or above	2	0	10	86				
9A	Ready-to-eat PHF/TCS Food held for more than 24 hours is date marked as required (prepared on-site)	48	43	3	4				
9B	Discard RTE PHF/TCS Food and/or opened commercial container exceeding 7 days at \leq 41°F (5°C) or 4 days at \leq 45°F (7°C)	41	22	34	1				
9C	Opened Commercial container of prepared ready-to-eat PHF/TCS Food is date marked as required	36	51	5	6				
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	2	2	0	94				
	Contaminated Equipment/Protection from Contam	inat	ion						
10A	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food	78	19	0	1				
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	65	8	1	24				
10C 10D	Food is protected from environmental contamination – critical items After being served or sold to a consumer, food is not re-served	83 98	15 0	0	0				
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	53	45	0	0				

DATA	DATA SSIMILATE (page 5 ST 4)							
ITEM	DATA ITEM	#	#	#	#			
#	DATATIEM	IN	OUT	NO	NA			
"	Poor Personal Hygiene							
12A	Hands are clean and properly washed when and as required	47	51	0	0			
127	Food Employees eat, drink, and use tobacco only in designated	77	31	0	- 0			
	areas/do not use a utensil more than once to taste food that is sold or							
	served / do not handle or care for animals present. Food employees							
	experiencing persistent sneezing, coughing, or runny nose do not							
	work with exposed food, clean equipment, utensils, linens,							
13A	unwrapped single-service or single-use articles	85	13	0	0			
444	Employees do not contact exposed, ready-to-eat food with their bare	00	_	_				
14A	hands.	90	6	1	1			
15A	Handwash facilities conveniently located and accessible for employees	81	17	0	0			
104	Handwash facilities supplied with hand cleanser/sanitary	01	17	0				
15B	towels/hand drying devices	85	13	0	0			
	Other/Chemical							
	If used, only approved food or color additives. Sulfites are not							
16A	applied to fresh fruits and vegetables intended for raw consumption	1	3	0	94			
	Poisonous or toxic materials, chemicals, lubricants, pesticides,							
	medicines, first aid supplies, and other personal care items are							
16B	properly identified, stored and used	72	26	0	0			
16C	Poisonous or toxic materials held for retail sale are properly stored	0	0	0	98			
17A	Supplemental Items – New Areas of Study	4	1	33	60			
1/A	Pork is cooked to 145°F (63°C) or above for 15 seconds	4	ı	აა	60			
17B	Ratites and injected meats are cooked to 155°F (68°C) for 15 seconds	1	0	8	89			
	PHF/TCS Food is maintained at 135°F (57°C) or above, except							
	during preparation, cooking, or cooling or when time is used as a							
18A	public health control	50	42	2	4			
	Facility has a written policy that is consistent with 2-201 of the Food							
	Code for excluding and restricting employees on the basis of their							
	health and activities as they relate to diseases that are transmissible							
	through food. Written policy includes a statement regarding employee responsibility to notify management of symptoms and							
19A	illnesses identified in the <i>Food Code</i> .	28	70	0	0			
	When packaged in a food establishment, juice is treated under a			Ť				
	HACCP Plan to reduce pathogens or be labeled as specified in the							
20A	Food Code	2	0	2	94			
	After receiving, raw shell eggs are immediately placed under							
04.4	refrigeration that maintains ambient air temperature of 45°F (7°C) or	_		40	70			
21A	less	0	0	19	79			
22A	After receipt, raw shell eggs are stored in refrigerated equipment that	16	0	4	78			
ZZA	maintains ambient air temperature of 45°F (7 °C) or less	10	U	4	70			

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	98
23B	Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls <i>Salmonella Enteritidis</i>	C	0	0	98
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	98

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA				
Food From Unsafe Sources									
1A	All food from Regulated Food Processing Plants/No Home prepared/canned foods	99	0	0	0				
1B	All shellfish from NSSP listed sources. No recreationally caught shellfish received or sold	8	1	0	90				
1C	Game, wild mushrooms harvested with approval of Regulatory Authority Food received at proper temperatures/protected from contamination	6	1	0	92				
2A	during transportation and receiving/food is safe, unadulterated Shellstock tags/labels retained for 90 days from the date the	99	0	0	0				
3A	container is emptied As required, written documentation of parasite destruction maintained	2	2	2	93				
3B	for 90 days for fish products CCP monitoring records maintained in accordance with HACCP plan	0	0	1	98				
3C	when required	1	1	0	97				
	Inadequate Cooking								
4A	Raw shell eggs broken for immediate service cooked to 145°F (63°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to155°F (68°C) for 15 seconds	0	0	0	99				
4B	Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for 15 seconds	0	0	3	96				
4C	Roasts, including formed roasts, are cooked to 130°F (54°C) for 112 minutes or as Chart specified and according to oven parameters per Chart	0	0	0	99				
4D	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds	0	0	2	97				
4E	Wild game animals cooked to 165°F (74°C) for 15 seconds	0	0	0	99				
4F	Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165°F (74°C). Food is allowed to stand covered for 2 minutes after cooking	0	0	0	99				
4G	Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds.	1	0	4	94				
4H	All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds PHF/TCS Food that is cooked and cooled on premises is rapidly	0	0	2	97				
5A 5B	reheated to 165°F (74°C) for 15 seconds for hot holding Food reheated in a microwave is heated to 165°F (74°C) or higher	0	0	0	97 99				
5C	Commercially processed ready-to-eat food, reheated to 140°F (60°C) or above for hot holding	0	0	1	98				
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	0	0	0	99				

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Improper Holding/Time & Temperature				
6A	Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F (21°C) within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6 hours	0	0	5	94
6B	PHF/TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours	11	1	21	66
6C	Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours	2	0	27	70
7A	PHF/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.	80	19	0	0
8 A	PHF/TCS Food is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.	0	2	1	96
8B	Roasts are held at a temperature of 130°F (54°C) or above	0	0	0	99
9A	Ready-to-eat PHF/TCS Food held for more than 24 hours is date marked as required (prepared on-site)	14	3	1	81
9B	Discard RTE PHF/TCS Food and/or opened commercial container exceeding 7 days at \leq 41°F (5°C) or 4 days at \leq 45°F (7°C)	13	2	5	79
9C	Opened Commercial container of prepared ready-to-eat PHF/TCS Food is date marked as required	5	4	3	87
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	0	0	0	99
	Contaminated Equipment/Protection from Contam	inat	ion		
10A	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food	58	16	0	25
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	74	25	0	0
10C 10D	Food is protected from environmental contamination – critical items	89 99	10	0	0
10D	After being served or sold to a consumer, food is not re-served Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	70	29	0	0

DATA ITEM	DATA ITEM	#	#	#	#					
#		IN	OUT	NO	NA					
	Poor Personal Hygiene									
12A	Hands are clean and properly washed when and as required	71	16	12	0					
	Food Employees eat, drink, and use tobacco only in designated									
	areas/do not use a utensil more than once to taste food that is sold or									
	served / do not handle or care for animals present. Food employees experiencing persistent sneezing, coughing, or runny nose do not									
	work with exposed food, clean equipment, utensils, linens,									
13A	unwrapped single-service or single-use articles	93	1	5	0					
	Employees do not contact exposed, ready-to-eat food with their bare									
14A	hands.	50	0	7	42					
15A	Handwash facilities conveniently located and accessible for Employees	93	6	0	0					
	Handwash facilities supplied with hand cleanser/sanitary									
15B	towels/hand drying devices	93	6	0	0					
	Other/Chemical									
	If used, only approved food or color additives. Sulfites are not									
16A	applied to fresh fruits and vegetables intended for raw consumption	0	0	0	99					
	Poisonous or toxic materials, chemicals, lubricants, pesticides,									
16B	medicines, first aid supplies, and other personal care items are properly identified, stored and used	85	14	0	0					
16C	Poisonous or toxic materials held for retail sale are properly stored	00	0	0	99					
	Supplemental Items – New Areas of Study			-						
17A	Pork is cooked to 145°F (63°C) or above for 15 seconds	0	0	4	95					
	Ratites and injected meats are cooked to 155°F (68°C) for 15									
17B	seconds	1	0	0	98					
	PHF/TCS Food is maintained at 135°F (57°C) or above, except									
404	during preparation, cooking, or cooling or when time is used as a			4	00					
18A	public health control Facility has a written policy that is consistent with 2-201 of the Food	1	1	1	96					
	Code for excluding and restricting employees on the basis of their									
	health and activities as they relate to diseases that are transmissible									
	through food. Written policy includes a statement regarding									
	employee responsibility to notify management of symptoms and									
19A	illnesses identified in the Food Code.	29	70	0	0					
	When packaged in a food establishment, juice is treated under a									
20A	HACCP Plan to reduce pathogens or be labeled as specified in the Food Code	0	0	0	99					
207	After receiving, raw shell eggs are immediately placed under		J		33					
	refrigeration that maintains ambient air temperature of 45°F (7°C) or									
21A	less	0	0	8	91					
	After receipt, raw shell eggs are stored in refrigerated equipment that									
22A	maintains ambient air temperature of 45°F (7°C) or less	8	0	0	91					

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.)				
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	99
23B	Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls <i>Salmonella Enteritidis</i>	0	0	0	99
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	99

DATA	DATA SOMMANT (page 1 of 4)								
DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA				
Food From Unsafe Sources									
	All food from Regulated Food Processing Plants/No Home	00							
1A	prepared/canned foods All shellfish from NSSP listed sources. No recreationally caught	80	2	0	0				
1B	shellfish received or sold	57	7	0	18				
	Game, wild mushrooms harvested with approval of Regulatory								
1C	Authority	0	0	0	82				
	Food received at proper temperatures/protected from contamination								
2A	during transportation and receiving/food is safe, unadulterated	79	3	0	0				
3A	Shellstock tags/labels retained for 90 days from the date the container is emptied	44	16	1	21				
<u> </u>	As required, written documentation of parasite destruction maintained	77	10	-					
3B	for 90 days for fish products	3	3	0	76				
	CCP monitoring records maintained in accordance with HACCP plan								
3C	when required	2	3	0	77				
	Inadequate Cooking								
	Raw shell eggs broken for immediate service cooked to 145°F (63°C)								
4A	for 15 seconds. Raw shell eggs broken but not prepared for	0	0	0	82				
4A	immediate service cooked to 155°F (68°C) for 15 seconds Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for	0	0	U	02				
4B	15 seconds	0	0	1	81				
	Roasts, including formed roasts, are cooked to 130°F (54°C) for 112								
	minutes or as Chart specified and according to oven parameters per								
4C	Chart	0	0	0	82				
	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,								
4D	stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds	0	0	1	81				
4E	Wild game animals cooked to 165°F (74°C) for 15 seconds	0	0	0	82				
	Raw animal foods cooked in microwave are rotated, stirred, covered,	Ť							
	and heated to 165°F (74°C). Food is allowed to stand covered for 2								
4F	minutes after cooking	0	0	6	76				
40	Pork, ratites, injected meats are cooked to 155°F (68°C) for 15	_	_	_	00				
4G 4H	seconds.	3	0	0 27	82 52				
4П	All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds PHF/TCS Food that is cooked and cooled on premises is rapidly	<u>ა</u>	U		32				
5A	reheated to 165°F (74°C) for 15 seconds for hot holding	0	0	1	81				
5B	Food reheated in a microwave is heated to 165°F (74°C) or higher	0	0	1	81				
	Commercially processed ready-to-eat food, reheated to 140°F (60°C)								
5C	or above for hot holding	0	0	1	81				
	Remaining unsliced portions of roasts are reheated for hot holding	_	_	_					
5D	using minimum oven parameters	0	0	0	82				

DATA	DATA GOMMANT (page 2 of 4)				
ITEM	DATA ITEM	#	#	#	#
#		IN	OUT	NO	NA
	Improper Holding/Time & Temperature				
	Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F (21°C)				
0.4	within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6	_			70
6A	hours	3	0	9	70
6B	PHF/TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours	5	4	18	55
00	Foods received at a temperature according to Law are cooled to 41°F			10	33
6C	(5°C) within 4 hours	3	0	46	33
	PHF/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				
7A	control.	67	15	0	0
	PHF/TCS Food is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a				
8A	public health control.	0	1	1	80
8B	Roasts are held at a temperature of 130°F (54°C) or above	0	0	0	82
	Ready-to-eat PHF/TCS Food held for more than 24 hours is date				
9A	marked as required (prepared on-site)	15	8	0	59
٥٦	Discard RTE PHF/TCS Food and/or opened commercial container	40		00	22
9B	exceeding 7 days at \leq 41°F (5°C) or 4 days at \leq 45°F (7°C) Opened Commercial container of prepared ready-to-eat PHF/TCS	18	8	23	33
9C	Food is date marked as required	20	26	3	33
	When time only is used as a public health control, food is cooked and				- 00
9D	served within 4 hours as required	0	1	0	81
	Contaminated Equipment/Protection from Contam	inati	ion		
	Food is protected from cross contamination by separating raw animal				
404	foods from raw ready-to-eat food and by separating raw animal foods		40		
10A	from cooked ready-to-eat food Raw animal foods are separated from each other during storage,	55	19	0	8
10B	preparation, holding, and display	50	11	0	21
10C	Food is protected from environmental contamination – critical items	75	7	0	0
10D	After being served or sold to a consumer, food is not re-served	82	0	0	0
44.	Food-contact surfaces and utensils are clean to sight and touch and	0.7			
11A	sanitized before use	67	15	0	0

DATA	DATA ITEM	щ	щ	щ	щ
ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
π	Poor Personal Hygiene	IIN	001	NO	IVA
12A	Hands are clean and properly washed when and as required	58	16	8	0
121	Food Employees eat, drink, and use tobacco only in designated				
	areas/do not use a utensil more than once to taste food that is sold or				
	served / do not handle or care for animals present. Food employees				
	experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens,				
13A	unwrapped single-service or single-use articles	72	4	6	0
1011	Employees do not contact exposed, ready-to-eat food with their bare				
14A	hands.	66	2	7	7
	Handwash facilities conveniently located and accessible for				
15A	Employees	76	6	0	0
15B	Handwash facilities supplied with hand cleanser/sanitary towels/hand drying devices	76	6	0	0
136	Other/Chemical	70	U	U	U
	If used, only approved food or color additives. Sulfites are not				
16A	applied to fresh fruits and vegetables intended for raw consumption	0	1	0	81
	Poisonous or toxic materials, chemicals, lubricants, pesticides,				
	medicines, first aid supplies, and other personal care items are				
16B	properly identified, stored and used	75	7	0	0
16C	Poisonous or toxic materials held for retail sale are properly stored	0	0	0	82
17A	Supplemental Items – New Areas of Study	0	0	0	82
1/A	Pork is cooked to 145°F (63°C) or above for 15 seconds Ratites and injected meats are cooked to 155°F (68°C) for 15	U	U	U	02
17B	seconds	0	0	0	82
	PHF/TCS Food is maintained at 135°F (57°C) or above, except				
404	during preparation, cooking, or cooling or when time is used as a	_		4	00
18A	public health control Facility has a written policy that is consistent with 2-201 of the Food	0	1	1	80
	Code for excluding and restricting employees on the basis of their				
	health and activities as they relate to diseases that are transmissible				
	through food. Written policy includes a statement regarding				
46.	employee responsibility to notify management of symptoms and				
19A	illnesses identified in the <i>Food Code</i> .	25	57	0	0
	When packaged in a food establishment, juice is treated under a HACCP Plan to reduce pathogens or be labeled as specified in the				
20A	Food Code	0	0	0	82
	After receiving, raw shell eggs are immediately placed under			Ť	
	refrigeration that maintains ambient air temperature of 45 °F (7 °C) or				
21A	less	0	0	0	82
22A	After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45°F (7°C) or less	0	0	0	82
<i></i>	maintains ambient air temperature of 45 F (1 G) of less	Ū	U	J	52

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.)				
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	82
23B	Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls <i>Salmonella Enteritidis</i>	C	0	0	82
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	82

APPENDIX I – PRODUCE

DATA ITEM	DATA ITEM	#	#	#	#				
#	D /(1/(11 L))	IN	OUT		NA				
Food From Unsafe Sources									
	All food from Regulated Food Processing Plants/No Home								
1A	prepared/canned foods All shellfish from NSSP listed sources. No recreationally caught	96	0	0	0				
1B	shellfish received or sold	0	0	0	96				
	Game, wild mushrooms harvested with approval of Regulatory								
1C	Authority	2	0	2	92				
2A	Food received at proper temperatures/protected from contamination during transportation and receiving/food is safe, unadulterated	93	3	0	0				
ZA	Shellstock tags/labels retained for 90 days from the date the	93		U	0				
3A	container is emptied	0	0	0	96				
	As required, written documentation of parasite destruction maintained								
3B	for 90 days for fish products	0	0	0	96				
3C	CCP monitoring records maintained in accordance with HACCP plan when required	0	0	0	96				
	Inadequate Cooking	Ŭ	Ū	Ū	00				
	Raw shell eggs broken for immediate service cooked to 145°F (63°C)								
	for 15 seconds. Raw shell eggs broken but not prepared for								
4A	immediate service cooked to155°F (68°C) for 15 seconds	0	0	0	96				
4B	Comminuted Fish, Meats, Game animals cooked to 155°F (68°C) for 15 seconds	0	0	2	94				
75	Roasts, including formed roasts, are cooked to 130°F (54°C) for 112		0		J-7				
	minutes or as Chart specified and according to oven parameters per								
4C	Chart	0	0	0	96				
	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,								
4D	stuffed ratites, or stuffing containing fish, meat, poultry or ratites cooked to 165°F (74°C) for 15 seconds	0	0	1	95				
4E	Wild game animals cooked to 165°F (74°C) for 15 seconds	0	0	0	96				
	Raw animal foods cooked in microwave are rotated, stirred, covered,								
	and heated to 165°F (74°C). Food is allowed to stand covered for 2	_							
4F	minutes after cooking	0	1	0	95				
4G	Pork, ratites, injected meats are cooked to 155°F (68°C) for 15 seconds.	0	0	0	96				
4H	All other PHF/TCS Food cooked to 145°F (63°C) for 15 seconds	0	0	0	96				
	PHF/TCS Food that is cooked and cooled on premises is rapidly								
5A	reheated to 165°F (74°C) for 15 seconds for hot holding	0	0	1	95				
5B	Food reheated in a microwave is heated to 165°F (74°C) or higher	0	0	6	90				
50	Commercially processed ready-to-eat food, reheated to 140°F (60°C)	4	_	2	00				
5C	or above for hot holding Remaining unsliced portions of roasts are reheated for hot holding	1	0	3	92				
5D	using minimum oven parameters	0	1	0	95				

APPENDIX I – PRODUCE

DATA SUMMARY (page 2 of 4)

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA		
Improper Holding/Time & Temperature							
6A	Cooked PHF/TCS Food is cooled from 140°F (60°C) to 70°F(21°C) within 2 hours and from 140°F (60°C) to 41°F (5°C) or below within 6 hours	0	0	2	94		
6B	PHF/TCS Food (prepared from ingredients at ambient temperature) is cooled to 41°F (5°C) or below within 4 hours	7	10	45	34		
6C	Foods received at a temperature according to Law are cooled to 41°F (5°C) within 4 hours	1	1	20	74		
7A	PHF/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.	46	50	0	0		
8A	PHF/TCS Food is maintained at 140°F (60°C) or above, except during preparation, cooking, or cooling or when time is used as a public health control.	9	0	1	86		
8B	Roasts are held at a temperature of 130°F (54°C) or above	0	0	0	96		
9A	Ready-to-eat PHF/TCS Food held for more than 24 hours is date marked as required (prepared on-site)	43	13	5	35		
9B	Discard RTE PHF/TCS Food and/or opened commercial container exceeding 7 days at \leq 41°F (5°C) or 4 days at \leq 45°F (7°C)	43	5	17	31		
9C	Opened Commercial container of prepared ready-to-eat PHF/TCS Food is date marked as required	13	7	6	70		
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	0	0	0	96		
Contaminated Equipment/Protection from Contamination							
10A	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food	6	1	1	88		
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	4	0	0	92		
10C	Food is protected from environmental contamination – critical items	84	12	0	0		
10D 11A	After being served or sold to a consumer, food is not re-served Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	96	35	0	0		

APPENDIX I – PRODUCE

DATA SUMMARY (page 3 of 4)

DATA	DATA COMMINATO (page 6 of 4)							
ITEM	DATA ITEM	#	#	#	#			
#	DATATIEM	IN	OUT	NO	NA			
Poor Personal Hygiene								
12A	Hands are clean and properly washed when and as required	49	16	31	0			
	Food Employees eat, drink, and use tobacco only in designated							
	areas/do not use a utensil more than once to taste food that is sold or							
	served / do not handle or care for animals present. Food employees							
	experiencing persistent sneezing, coughing, or runny nose do not							
13A	work with exposed food, clean equipment, utensils, linens,	64	7	25	0			
13A	unwrapped single-service or single-use articles Employees do not contact exposed, ready-to-eat food with their bare	04		25	0			
14A	hands.	60	4	28	4			
17/	Handwash facilities conveniently located and accessible for	- 00		20				
15A	Employees	81	15	0	0			
	Handwash facilities supplied with hand cleanser/sanitary							
15B	towels/hand drying devices	79	17	0	0			
Other/Chemical								
	If used, only approved food or color additives. Sulfites are not							
16A	applied to fresh fruits and vegetables intended for raw consumption	3	1	0	92			
	Poisonous or toxic materials, chemicals, lubricants, pesticides,							
16B	medicines, first aid supplies, and other personal care items are properly identified, stored and used	78	18	0	0			
16C	Poisonous or toxic materials held for retail sale are properly stored	95	10	0	0			
100	Supplemental Items – New Areas of Study	00	'	Ū	U			
17A	Pork is cooked to 145°F (63°C) or above for 15 seconds	0	0	0	96			
	Ratites and injected meats are cooked to 155°F (68°C) for 15							
17B	seconds	0	0	0	96			
	PHF/TCS Food is maintained at 135°F (57°C) or above, except							
	during preparation, cooking, or cooling or when time is used as a				0.0			
18A	public health control	9	0	1	86			
	Facility has a written policy that is consistent with 2-201 of the <i>Food Code</i> for excluding and restricting employees on the basis of their							
	health and activities as they relate to diseases that are transmissible							
	through food. Written policy includes a statement regarding							
	employee responsibility to notify management of symptoms and							
19A	illnesses identified in the <i>Food Code</i> .	27	69	0	0			
	When packaged in a food establishment, juice is treated under a							
	HACCP Plan to reduce pathogens or be labeled as specified in the							
20A	Food Code	2	1	1	92			
	After receiving, raw shell eggs are immediately placed under							
24.4	refrigeration that maintains ambient air temperature of 45°F (7°C) or	^	0	22	71			
21A	less After receipt, raw shell eggs are stored in refrigerated equipment that	0	0		74			
22A	maintains ambient air temperature of 45°F (7°C) or less	19	3	1	73			
22 M	maintains ambient ail temperature 01 45°F (1°C) 01 less	ıΰ	J	l I	13			

APPENDIX I – PRODUCE

DATA SUMMARY (page 4 of 4)

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA	
Supplemental Items – New Areas of Study (cont.)						
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	96	
23B	Pasteurized eggs or egg products substituted for raw shell eggs in preparation of foods that are not cooked to minimum required temperatures, (specified in Section 4.0 of this data collection form), unless cooked to order & immediately served; broken immediately before baking and thoroughly cooked; or included as an ingredient for a recipe supported by a HACCP plan that controls <i>Salmonella Enteritidis</i>	0	0	0	96	
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	96	

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APPENDIX K - RESOURCES

WEB SITE LOCATIONS FOR REFERENCED DOCUMENTS

1997 FDA Food Code

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode1997/default.htm

2001 FDA Food Code

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2001/default.htm

2003 Supplement to the 2001 FDA Food Code

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2001/ucm089117.htm

2005 FDA Food Code

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2005/default.htm

Supplement to the 2005 FDA Food Code

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2005/ucm124080.htm

FDA CFSAN Retail Food Protection

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

<u>FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional</u> Foodservice, Restaurant, and Retail Food Store Facility Types (2004)

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodbornellInessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm089696.htm

FDA Voluntary National Retail Food Regulatory Program Standards

www.fda.gov/Food/FoodSafety/RetailFoodProtection/ProgramStandards/ucm124968.htm

Gateway to Government Food Safety Information

www.foodsafety.gov

Government Performance and Results Act of 1993

www.whitehouse.gov/omb/mgmt-gpra/gplaw2m.html

<u>Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators</u> of Food Service and Retail Establishments

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/default.htm

APPENDIX K - RESOURCES

WEB SITE LOCATIONS FOR REFERENCED DOCUMENTS

<u>Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-Based</u>
<u>Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management</u>
<u>Systems</u>

http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/default.htm

<u>Reinventing Food Regulations (1996), National Performance Report http://govinfo.library.unt.edu/npr/library/rsreport/foodreg.html</u>

Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000) http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm123544.htm

<u>Surveillance for Foodborne Disease Outbreaks --- United States, 1988—1992, Center for Disease Control and Prevention</u>

http://www.cdc.gov/mmwr/preview/mmwrhtml/00044241.htm