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

Prepared by the FDA National Retail Food Team

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EXECUTIVE SUMMARY

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

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

For the purposes of this long-term study, FDA designates these contributing factors as "foodborne illness risk factors."

The first report in the study was issued in August 2000 and presented data collected in 1998. This 2004 report is the second report in the series and presents data collected in 2003. A third data collection is scheduled for 2008.

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

In 2003, FDA Regional Retail Food Specialists collected data during site-visits of over 900 establishments representing nine distinct facility types. Direct observations, supplemented with information gained from discussions with management and food workers, were used to document the establishments' compliance status for forty-two 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 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 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.

The data presented in this report indicate that the same risk factors and data items identified as problem areas in the 2000 report remain in need of priority attention. This indicates that industry and regulatory efforts to promote active managerial control of these risk factors must be strengthened. In all facility types, 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/Prevention of 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) and inadequate date marking of refrigerated ready-to-eat PHF.

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 34% for hospital foodservice to approximately 73% 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 each facility type. Percent Out of Compliance values for this data item ranged from 25% in elementary schools to 58% in deli departments.

This report also 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 data suggests that the presence of a certified manager has a positive effect on the control of certain risk factors, especially in fast food restaurants, full service restaurants, meat and poultry departments, and produce departments. Poor personal hygiene appears to be the risk factor for which the presence of a certified manager had the most positive effect.

The 2003 data collection effort included several supplemental data items that were not included in the 1998 data collection. While the forty-two primary data items in the study remained the same from 1998 to 2003, the supplemental data items addressed changes made to the *FDA Food Code* since 1998. These items related to the cooking temperature for pork, 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 potentially hazardous foods from 140 $^{\circ}$ F (60 $^{\circ}$ C) to 135 $^{\circ}$ F (57 $^{\circ}$ C) and reducing the minimum cooking temperature for pork from 155 $^{\circ}$ F (68 $^{\circ}$ C) to 145 $^{\circ}$ F (63 $^{\circ}$ C) had minimal effect on the industry's control of these risk factors.

Results from the 2003 data collection indicate that the recommendations made to foodservice and retail food operators and regulators in the 2000 Report need to be reemphasized. Foodservice and retail food 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 are directed toward developing a national retail food program model that can 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 mechanism 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* identified the food preparation practices and behaviors most often associated with foodborne illness outbreaks. These reported contributing factors relate to food safety concerns within foodservice and retail food store facility types and include:

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

For the purposes of this long-term study, FDA designated these five categories of contributing factors as "foodborne illness risk factors." Note that this use of the term "risk factor" should not be confused with another use of the same phrase to describe characteristics of the person, food or location that are statistically linked to illness by an epidemiological investigation. 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 forty-two data items related to foodborne illness risk factors in institutional foodservice, restaurants, and retail food 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 operations have control over the risk factors during each data collection period. Using the data from multiple collection periods, FDA hopes to evaluate trends and determine whether progress is being made toward the goals of reducing the occurrence of foodborne illness risk factors.

In order to detect trends of improvement and/or regression in this study, it is necessary to collect data from at least three, and preferably more, periods in time.

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 2 nd of at least three sets of data needed to assess trends in occurrence of risk factors.
2008	Target Report Date: 2009	Use the information from the three data sets to assess improvement/regression changes from the 1998 Baseline

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 forty-two 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

referriage (70) of Observations found in Compliance for ALL Data items				
		1998 Baseline*	2010	
		% IN Compliance	FDA	
Industry	Facility	for Observations	Improvement	
Segment	Туре	made of ALL	Goal**	
		data items	(rounded to	
		(rounded to	nearest %)	
		nearest %)		
Institutions	Hospital	80%	85%	
	Nursing Home	82%	87%	
	Elementary School	80%	85%	
Restaurants	Fast Food	74%	81%	
	Full Service	60%	70%	
Retail Food	Deli	73%	80%	
	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

2003 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 (2004) summarizes results from the second data collection conducted in 2003. 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 and foodservice operations. This report should be read and the data interpreted as a separate stand-alone report. Additional data are needed before any meaningful assessments of trends can be made for each of the facility types. This report makes no attempt to draw comparisons between the results of the 1998 and 2003 data collections.

2008 Study will begin the process for assessing risk factor changes

A third data collection is planned for 2008. Having data from three separate years over a ten-year span should shed light on whether changes in the occurrence of risk factors in foodservice and retail food establishments are taking place.

B. Study Design and Objectives

This study contains nine separate baselines, 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. Not only would it be inappropriate from a statistical standpoint, but such comparisons might be combined with other information, such as the location of FDA Regional Retail Food Specialists, to identify some of the establishments eligible for random selection in future studies. This information would bias later data collection efforts.

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. Introduction

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 2003 study has been designed to do and, equally important, what it is 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 IN Compliance of 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 if 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 17 to 25) 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 forty-two data items will remain 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, New Areas of Study – Supplemental Data Items.

The study was not designed to measure regulatory compliance with specific state or local Food Codes

The forty-two data items used to track changes in the occurrence of foodborne illness risk factors were based on the provisions within the *1997 FDA Food Code*. No attempt was made to determine if an establishment would have been found to be substantially 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 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 and 2003 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.

For example, improper handwashing, which falls under the Poor Personal Hygiene risk factor, is associated with the spread of pathogens. There is a direct link between improper handwashing and potential human illness. The Poor Personal Hygiene risk factor also included data items related to the availability of hand soap and sanitary towels/hand drying devices. 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.

Each of the risk factors in this report included individual data items that had a direct link to human illness and/or industry management practices essential to their control. For instance, the retention of shellstock tags was included in the evaluation of food source and date marking of ready-to-eat potentially hazardous foods was part of an assessment of holding 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 2003 report covered 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 Designed to:	The Study IS NOT Designed to			
Measure trends over time in regulatory & industry efforts to reduce the occurrence of foodborne illness risk factors Assess the occurrence of foodborne illness risk factors and management practices essential to their control in selected institutional foodservice, restaurant and retail food facility types	Support comparisons of geographic areas, states, counties, cities or chains of foodservice/retail food store operations 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 & 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 disease 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 every data collection. For the 2003 data collection period, supplemental data items have been added to capture additional information not collected in 1998. The following sections of the report will present an overview of the methodology used in this study as originally designed in 1998. In addition, unique elements to the 2003 data collection (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 industry.

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 was a group of persons who are more likely than the general population to experience foodborne disease due to their current health status or age.

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 (1 or 2 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 1 or 2 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 2 or 3 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.	

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, 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

Approximately twenty 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 retail food industry 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, which would have been cost-prohibitive and eliminated other vital work by FDA.

E. <u>Selection of Establishments Using Comparison Set</u> Establishment Lists

For the 1998 data collection period, each Specialist developed 5 Comparison Set Establishment 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. In order to maintain data reliability and to ensure confidentiality of the selected establishments, the comparison set lists, as well as the inspectional observations, were retained in a central database by number rather than by establishment name or location.

Table 5 provides an illustration of a hypothetical Comparison Set Establishment List

Table 5

Comparison Set Establishment 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 # Chosen?	Inspected?
1. Anytime Food	1 Ocean Dr., Ocean Park, IL	123-4561		
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.

In order to maintain consistency between data collection periods, the Specialists used the 1998 Comparison Set Establishment Lists in 2003 and will use them again in 2008. Selection bias was prevented by using a random number table to choose the establishments that were to be inspected. For example, using the hypothetical Comparison Set Establishment List, the Hungry Horses establishment was selected and inspected in 1998. In 2003, Zesty Delights was selected at random but was not inspected because it had gone out of business. Thus, the Specialist randomly selected another establishment from the list – Crazy Time Food.

Only one establishment was inspected from each comparison set list during the data collection. In addition, an establishment on a comparison set list could only be selected once for inspection. For instance, if in 2003, a Specialist randomly-picked an establishment that had already been inspected in 1998, the Specialist would have had to draw another random number until an establishment on the comparison set list that had not been inspected was chosen.

F. Number of Inspections Conducted

For statistical purposes at least ninety inspections were needed for each facility type. At least 100 inspections per facility type were planned to allow for un expected difficulties. In 2003, a total of 926 inspections, consisting of 15,516 observations, were conducted by FDA Regional Retail Food Specialists. Based on the number of inspections planned, each Specialist had to inspect at least five establishments from each of the nine facility types for a total of forty-five 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 what particular behavior or practice was at risk, there were twelve different types of observations that could be made, each corresponding to its own data item.

The data collection form used in 1998 included forty-two individual data items sorted among the five foodborne illness risk factors and a sixth category, "Other," for the potential risks related toxic or unapproved chemicals. Each of the forty-two data items were based on the 1997 FDA Food Code for both data collection periods.

The Food Code has and will continue 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 forty-two data items; others are new provisions used to address emerging food safety concerns. To capture data for these changes, an additional category, "Supplemental Data Items," was added to the data collection form in 2003. The requirements in the 2001 Food Code were used as the basis for the Supplemental Data Items.

The following Data Collection Form was used for each establishment that was inspected:

BASELINE DATA COLLECTION FORM (page 1 of 9)

This form was drafted for the specific purpose of collecting data regarding the occurrence at the retail level of risk factors associated with foodborne illness outbreaks. It was/is not intended to serve as a comprehensive, Food Code-based inspection form for food establishments.

Baseline Data Collection Form

Food and Drug Administration, Division of Cooperative Programs
Baseline Data Collection Project

Date:					
Time In: Inspector:					
Data Collected During:					
Establishment: Manager: Physical Address:					
City:	Audress.		Industry Segment:		
State:	Zip:	County:	Facility Type:		
Certified	Food Prot	ection Manager:	YES NO		
		or45 °F (7 °C) onent for this jurisdiction	or 41 °F (5 °C) + 45 °F (7 °C) is the on.		
		RVATIONS:			
IN =			Compliance marking must be based on		
OUT =		servations)	(Out of Compliance marking must be		
001 =		actual observations)	(Out of Comphance marking must be		
NO =		,	s made when the data item is part of the		
			rocedures, OR is seasonal and is not		
NI A		at the time of the ins			
NA =	 Not applicable (NA marking is made when the data item is NOT part of the establishment's operation or procedures) 				
		DICK	FACTORS		
	RI		FACTORS OS FROM UNSAFE SOURCE		
FOOD SOURCE					
STATUS 1. Approved Source					
IN OUT		All food from Regulat	ed Food Processing Plants/ No home		
IN OUT N			SP listed sources. No recreationally		
		caught shellfish recei	ved or sold		
IN OUT N	N OUT NA NO C. Game, wild mushrooms harvested with approval of Regulatory Authority				

BASELINE DATA COLLECTION FORM (page 2 of 9)

STATUS 2. Receiving / Sound Condition

IN OUT A. Food

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

RISK FACTOR-INADEQUATE COOK

PATHOGEN DESTRUCTION

STATUS

- 4. Proper Cooking Temperature Per Potentially Hazardous Food (PHF). (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 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 to 155 °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).

BASELINE 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 °F (74 °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 cooked to 145 °F (63 °C) for 15 seconds

STATUS 5. Rapid Reheating For Hot Holding

- **IN OUT NA NO** A. PHF 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

BASELINE DATA COLLECTION FORM (page 4 of 9)

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 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 (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 Baseline, 41 °F (5 °C) or below will be used as the criteria for assessing all PHF that are maintained/held cold.) If one product is found out of temperature the item is marked Out of Compliance.) IN OUT A. PHF 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.)

BASELINE DATA COLLECTION FORM (page 5 of 9)

STATUS 8. Hot Hold (140 °F (60 °C))

IN OUT NA NO A. PHF 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. (NOTE: Products held between 135 °F (57 °C) and 140 °F (60 °C) should be marked OUT in 8A, but IN 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 held for more than 24 hours is date marked as required (prepared on-site)
- IN OUT NA NO B. Discard RTE PHF and/or opened commercial container exceeding 7 days at \leq 41 °F (5 °C) or 4 days at \leq 45 °F (7 °C)
- **IN OUT NA NO** C. Opened Commercial container of prepared ready-to-eat PHF 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

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 NA NO** D. After being served or sold to a consumer, food is not reserved

BASELINE 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

A. Food-contact surfaces and utensils are clean to sight and touch and sanitized before use

RISK FACTOR-POOR PERSONAL HYGIENE

PERSONNEL

STATUS 12. Proper, Adequate Handwashing

IN OUT

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 singleuse articles

BASELINE 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

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

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23

BASELINE DATA COLLECTION FORM (page 8 of 9)

SUPPLEMENTAL ITEMS

(NOTE: The following items will be included as part of FDA's 2003 Baseline. These are additional items to the original 42 data item (contained in Section 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 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

A. 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*.

BASELINE 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. STATUS 22. Cold Holding – Raw Shell Eggs **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 Baseline 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	Risk Factor
FOODS FROM UNSAFE SOURCES	INADEQUATE COOK
Food Source	Pathogen Destruction
1. Approved Source	4. Proper Cooking Temperature per PHF
Data Harry 4.4	Data Harry 4A
<u>Data Item - 1A</u> 3-201.11* Compliance with Food Law	<u>Data Item – 4A</u> 3-401.11(A)(1)(a)* Raw Animal Foods
3-201.11* Compliance with 1 ood Law 3-201.12* Food in A Hermetically Sealed	3-401.11(A)(1)(a) Raw Allimai Foods
Container.	0 401.11(/1)(2) 11aw / 11iiiiiai 1 0000
3-201.13* Fluid Milk and Milk Products	Data Item – 4B
	3-401.11(A)(2)* Raw Animal Foods
<u>Data Item – 1B</u>	
3-201.14* Fish	Data Item – 4C
3-201.15* Molluscan Shellfish	3-401.11(B)(1)(2)* Raw Animal Foods
3-202.18* Shellstock Identification	Data Item – 4D
Data Item – 1C	3-401.11(A)(3)* Raw Animal Foods
3-201.16* Wild Mushrooms	0 401.11(/t)(0) 1\taw /\taw
3-201.17* Game Animals	Data Item – 4E
	3-401.11(A)(3)* Raw Animal Foods
2. Receiving/Sound Condition	
	Data Item – 4F
<u>Data Item – 2A</u>	3-401.12* Microwave Cooking
3-202.11* Temperature 3-202.15* Package Integrity	Data Item – 4G
3-101.11* Safe, Unadulterated, and Honestly	3-401.11(A)(2)* Raw Animal Foods
Presented	0 10 1111(1)(<u>1</u>) 11an 7 mmar 1 0000
	<u>Data Item – 4H</u>
	3-401.11(A)(1)(b)* Raw Animal Foods
3. Records	5. Rapid Reheating for Hot Holding
Data Item 2A	Data Item 5A
<u>Data Item – 3A</u> 3-202.18* Shellfish Identification	Data Item 5A 3-403.11(A)* Reheating for Hot Holding
3-203.12* Shellfish Maintaining Identification	3 700.11(A) INCHEATING TO FIGURING
5 255.12 Shomes markaning identified to it	Data Item 5B
Data Item – 3B	3-403.11(B)* Reheating for Hot Holding -
3.402.11* Parasite Destruction	Microwave
3.402.12* Records, Creation and Retention	
Data Maria 20	Data Item 5C
<u>Data Item – 3C</u> 3-502.12* Reduced Oxygen Packaging,	3-403.11(C)* Reheating for Hot Holding – Commercially Processed RTE
Criteria	Food
8-103.12* Conformance with Approved	1 000
Procedures	Data Item 5D
	3-403.11(E)* Reheating for Hot Holding –
	Remaining sliced portions roasts
	Of beef

REFERENCE SHEET (page 2 of 5)

1997 FDA Food Code used for Original 42 Individual Data Items

Risk Factor IMPROPER HOLD Limitation of Growth of Organisms of Public Health Concern	Risk Factor IMPROPER HOLD Limitation of Growth of Organisms of Public Health Concern
6. Proper Cooling Procedure	9. Time
Data Item 6A 3-501.14(A)* Cooling – Cooked PHF Data Item 6B 3-501.14(B)* Cooling – BHE proposed from	Data Item 9A 3-501.17(A)(1)(2)* Ready-to-Eat, PHF, Date Marking – On-premises Preparation (Food is to be data marked at the time of preparation
3-501.14(B)* Cooling – PHF prepared from ingredients at ambient temperature	 (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) ≤ 7 calendar days at 41°F (5°C) or less; or
3-501.14(C)* Cooling – PHF 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, Disposition (Food shall be discarded if not consumed within ≤ 7
7. Cold Hold (41 $^{\circ}$ F (5 $^{\circ}$ C))	calendar days at 41 °F (5 °C) or less; or ≤ 4 calendar days at 45 °F (7 °C))
Data Item 7A 3-501.16(B)* PHF, Hot and Cold Holding (For the purposes of this Baseline, 41°F (5°C) or below will be used as the criteria for assessing all PHF that are maintained/held cold.) 8. Hot Hold (140°F (60°C)) Data Item 8A 3-501.16(A)* PHF, Hot and Cold Holding	Data Item 9C 3-501.17(C)* Ready-to-Eat, PHF, 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: (1) \leq 7 calendar days at 41° F (5°C) or less; or
Data Item 8B 3-501.16(A)* PHF, Hot and Cold Holding 3-501.16(A)* PHF, Hot and Cold Holding	 (2) ≤ 4 calendar days at 45° F (7°C)) Data Item 9D 3-501.19* Time as a Public Health Control

REFERENCE SHEET (page 3 of 5)

1997 FDA Food Code used for Original 42 Individual Data Items

Risk Factor CONTAMINATED EQUIPMENT Protection from Contamination	Risk Factor POOR PERSONAL HYGIENE 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)	Data Item 12A 2-301.11* Clean Condition 2-301.12* Cleaning Procedure 2-301.14* When to Wash 2-301.15* Where to Wash
,	13. Good Hygiene Practices
Data Item 10B 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 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
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	14. Prevention of Contamination from Hands Data Item 14A 3-301.11* Preventing Contamination from Hands
Data Item 10D 3-306.14(A)(B)* Returned Food, Reservice or 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	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
4-702.11* Sanitization of Equipment and Utensils – Before Use After Cleaning	<u>Data Item 15B</u> 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 Suppliers 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	SUPPLEMENTAL ITEMS
17. Proper Cooking Temperature (supplement to 4G – 2001 FDA Food Code)	23. Food & Food Preparation for Highly Susceptible Populations – 2001 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
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 – 2003 Supplement to the 2001 FDA Food Code)	<u>Data Item 23C</u> 3-801.11(D)* Prohibited Foods
Data Item 18A 3-501.16(A)(1)* PHF, Hot and Cold Hold	<u>LEGEND</u>
19. Written Employee Health Policy (NOTE: 2001 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	C = Celsius F = Fahrenheit RTE = Ready-to-Eat PHF = Potentially Hazardous Food R.A. = Regulatory Authority
20. Treating Juice – 2001 FDA Food Code Data Item 20A	
21. Cooling Raw Shell Eggs – 2001 Food Code	
<u>Data Item 21A</u> 3-501.14(D)* Cooling	
22. Cold Holding – Raw Shell Eggs – 2001 FDA Food Code	
<u>Data Item 22A</u> 3-501.16(B) Hot and Cold Holding	

H. <u>Data Collection Procedure</u>

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 a Specialist. 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 various 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 forty-two individual data items and the 2001 FDA Food Code/2003 Food Code Supplement 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 is based on an evaluation of one or more occurrences of a data item at an establishment. If all observed occurrences are IN Compliance, the data item is marked "IN". If any observed occurrence is Out of Compliance, then the data item is marked "OUT".

- IN meaning that the observation was IN COMPLIANCE with applicable FDA Food Code provisions;
- OUT meaning that the observation was OUT OF COMPLIANCE with applicable FDA Food Code provisions. An explanation of the observation was provided in the comment sections on the data collection form;
- N.O. meaning 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 service operation, 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.; or
- N.A. meaning the data item was NOT APPLICABLE. The N.A. notation was
 used when a data item was not part of the food service operation. For example, if
 a seafood department that conducts no cooking was selected for the study, then
 all data items pertaining to cooking were marked N.A.

The Specialists were provided specific instructions for using the four marking options for each of the data items. 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 held PHF cold. 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 were 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 were the case, the overall IN Compliance measurement for the establishment would have been higher than what was documented by actual observation of the food safety practice or employee behavior and would have been an over-estimate.

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 documented by actual observation of the food safety practice or employee behavior and would have been an over-estimate.

The Specialists were provided a copy of a software program customized to store and analyze 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 was sent to FDA headquarters for entry 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/ Division of Mathematics 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 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	155
ELEMENTARY SCHOOLS	99
NURSING HOMES	129
FAST FOOD RESTAURANTS	87
FULL SERVICE RESTAURANTS	133
DELI	94
MEAT & POULTRY	48
SEAFOOD	56
PRODUCE	41

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 in most 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 most often implicated as the cause of foodborne illness. 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 results of the 2003 study are presented in three parts for each of the facility types.

- 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 comprises a risk factor
- Part C. Summarizes the risk factors and individual data items needing priority attention

The results will be presented separately for each of the facility 9 types.

The figures presented in this section for each of the facility types include only observations from the original forty-two data items used in the 1998 baseline collection. These forty-two data items will be used to measure improvement and/or regression changes in the occurrence of foodborne illness risk factors for the duration of this study. None of the Supplemental data items (Sections 17-23 of the data collection form) 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, New Areas of Study – Supplemental Data Items.

Using the Data Collection Form (Pages 17 - 25) 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	5	Sections 10 – 11
Contamination		
Poor Personal Hygiene	5	Sections 12 – 15
Other (Chemical Contamination)	3	Section 16
TOTAL NUMBER OF DATA ITEMS	42	

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

Table 8

Formula for Calculating RISK FACTOR Out of Compliance Percentages

Percent Out of Compliance =

Total Number of Out of Compliance observations for a risk factor X 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 2003 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. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

Table 9

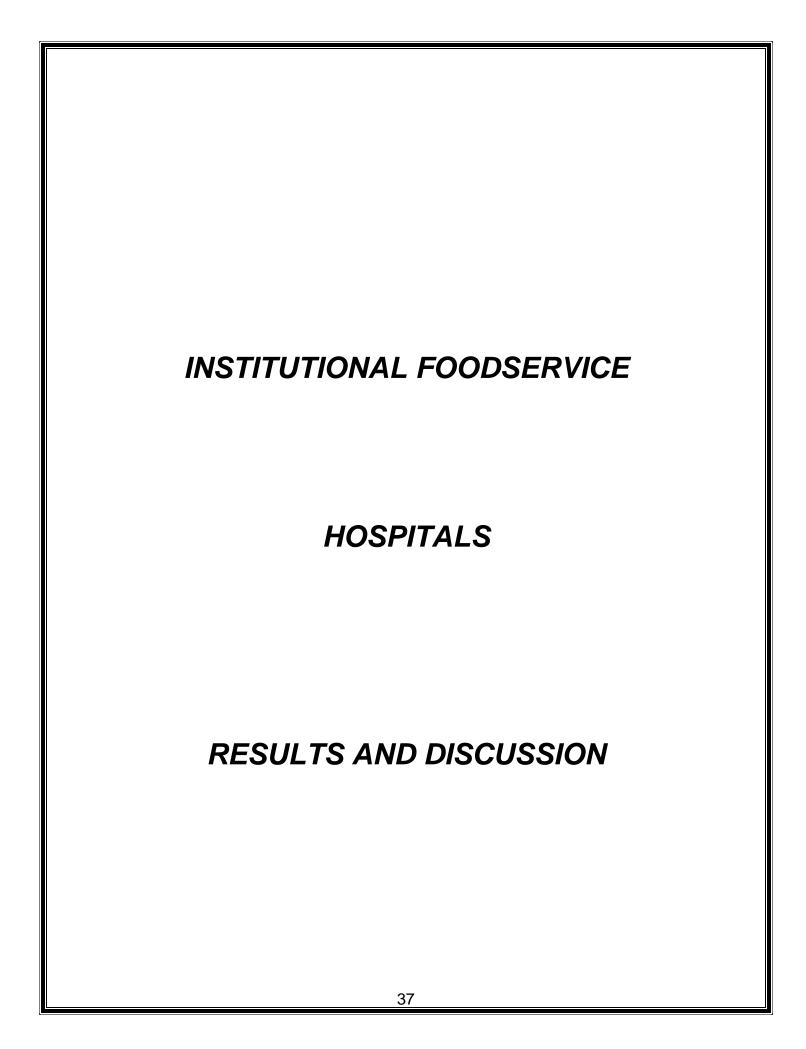
Formula for Calculating Out of Compliance Percentages for each DATA ITEM that Comprises a Risk Factor

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.

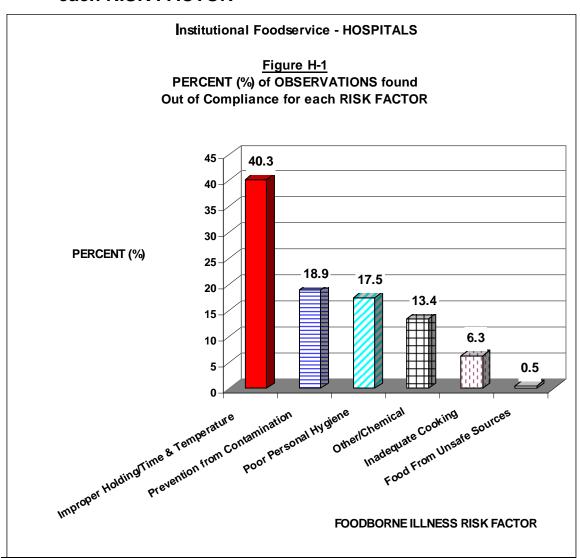
The figures in this section contain only those data items with the highest Out of Compliance percentages. In a few cases, there are one or more data items that warrant attention within a risk factor that had a relatively high overall IN Compliance percentage. For these data items, the results of the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

C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL 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 2003 data collection are presented in the summary section.



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	212	526	40.3%
Contaminated Equipment/Protection from Contamination	86	456	18.9%
Poor Personal Hygiene	84	480	17.5%
Other/Chemical	17	127	13.4%
Inadequate Cooking	16	255	6.3%
Food From Unsafe Sources	1	194	0.5%

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 and poor personal hygiene 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 when compared to the other risk factors evaluated during this data collection period. In general, the other/chemical risk factor had a high IN Compliance percentage.

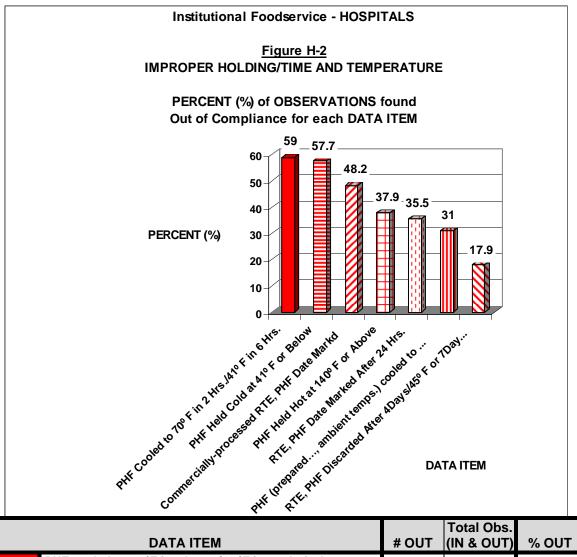
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

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

- Improper Hold/Time and Temperature (40.3%)
- Contaminated Equipment/Protection from Contamination (18.9%)
- Poor Personal Hygiene (17.5%)

Figures H-2 thru H-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 hospitals to control each of the risk factors during the 2003 data collection.

In general, the other/chemical risk factor had a high IN Compliance percentage. There was, however, one data item within this risk factor 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 will be presented.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	PHF cooled to 70 °F in 2 hours/41 °F in total of 6 hours	23	39	59.0%
	PHF held cold at 41 °F or below	56	97	57.7%
	Commercially-processed, RTE, PHF date marked	41	85	48.2%
	PHF held hot at 140 °F or above	36	95	37.9%
	RTE, PHF date marked after 24 hours	33	93	35.5%
	PHF(prepared from ingredients at ambient temperature) cooled to 41 °F or below within 4 hours	9	29	31.0%
	RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F	12	67	17.9%
*	Foods received at temperatures according to Law are cooled to 41 °F within 4 hours.*	2*	14*	*
*	Roasts are held at a temperature of 130 °F or above*	0*	5*	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0*	2*	*

^{*} These three remaining 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:

- Cooling of potentially hazardous food (PHF) (59.0%)
- Maintaining cold holding temperatures for PHF (57.7%)
- Date marking of open containers of commercially-processed ready-to-eat PHF (48.2%) and ready-to eat PHF made on-site (35.5%)
- Maintaining hot holding temperatures for PHF (37.9%)

Cooling of PHF

Safe cooling requires the removal of heat from foods quickly enough to prevent the growth of spore-forming pathogens. Hospital foodservice directors and managers need to ensure their practices and procedures are capable of rapidly cooling PHF.

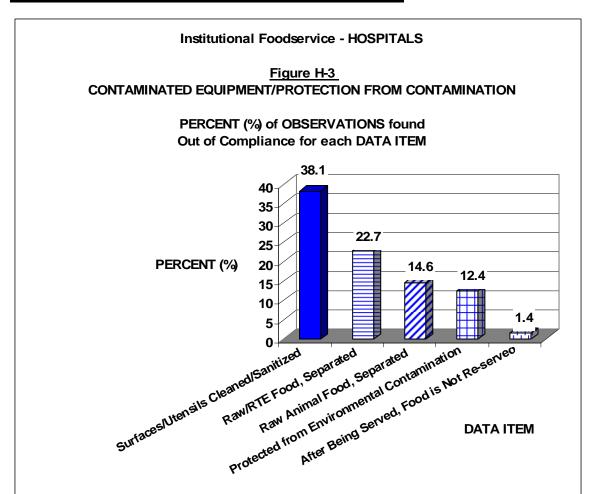
The total number of observations for cooling was substantially less than the total number of observations for other data items. The time of day the data was collected and the length of the time available to spend in a facility were significant factors limiting the number of observations of cooling. For example, as much as six hours may be required on site to document compliance with the *FDA Food Code* critical limits for cooling. Nonetheless, observations made of cooked or reheated PHF during cooling had the highest Out of Compliance percentage. In addition, the Percent Out of Compliance for cooling PHFs 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

Holding PHF 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 need to be assessed and corrective action should be taken if necessary.

Date Marking

Date marking of refrigerated ready-to-eat, PHF foods is an important food safety system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF 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. The importance of date marking of ready-to-eat, PHF is accentuated in the hospital environment because the meals are primarily served to a highly susceptible population.



DATA ITEM	# OUT	Total Obs.	0/ OUT
DATA ITEM	# OUT	(IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	37	97	38.1%
Raw/RTE foods, separated	22	97	22.7%
Raw animal food, separated	14	96	14.6%
Protected from environmental contamination	12	97	12.4%
After being served, food is not re-served	1	69	1.4%

Discussion for Figure H-3

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

- Cleaning and sanitizing food contact surfaces and utensils (38.1%)
- Separating raw animal foods from ready-to-eat foods (22.7%)
- Separating raw animal foods from each other (14.6%)

Cleaning and Sanitizing

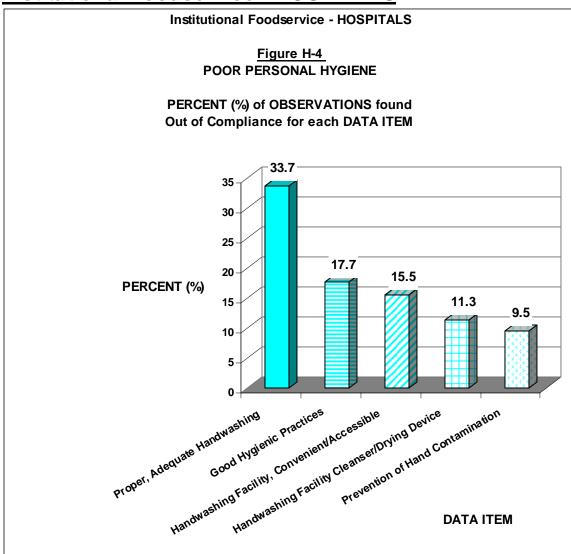
Proper cleaning and sanitization of food contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and stand-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 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. 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. Having organized storage systems that include designated areas for 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	32	95	33.7%
Good hygienic practices	17	96	17.7%
Handwashing facility, convenient/accessible	15	97	15.5%
Handwashing facility, cleanser/drying device	11	97	11.3%
Prevention of hand contamination	9	95	9.5%

Discussion for Figure H-4

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

- Proper, adequate handwashing (33.7%)
- Good hygienic practices (17.7%)

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 the lack of proper 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 2003 study show a relatively high IN Compliance percentage (90.5%) for preventing direct hand contamination of food in hospitals. Hospital foodservice managers appear to be making a concerted effort to eliminate bare hand contact with ready-to-eat foods.

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 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

# Observations	TOTAL Observations	% Observations
OUT	(IN & OUT)	OUT
17	97	17.5%

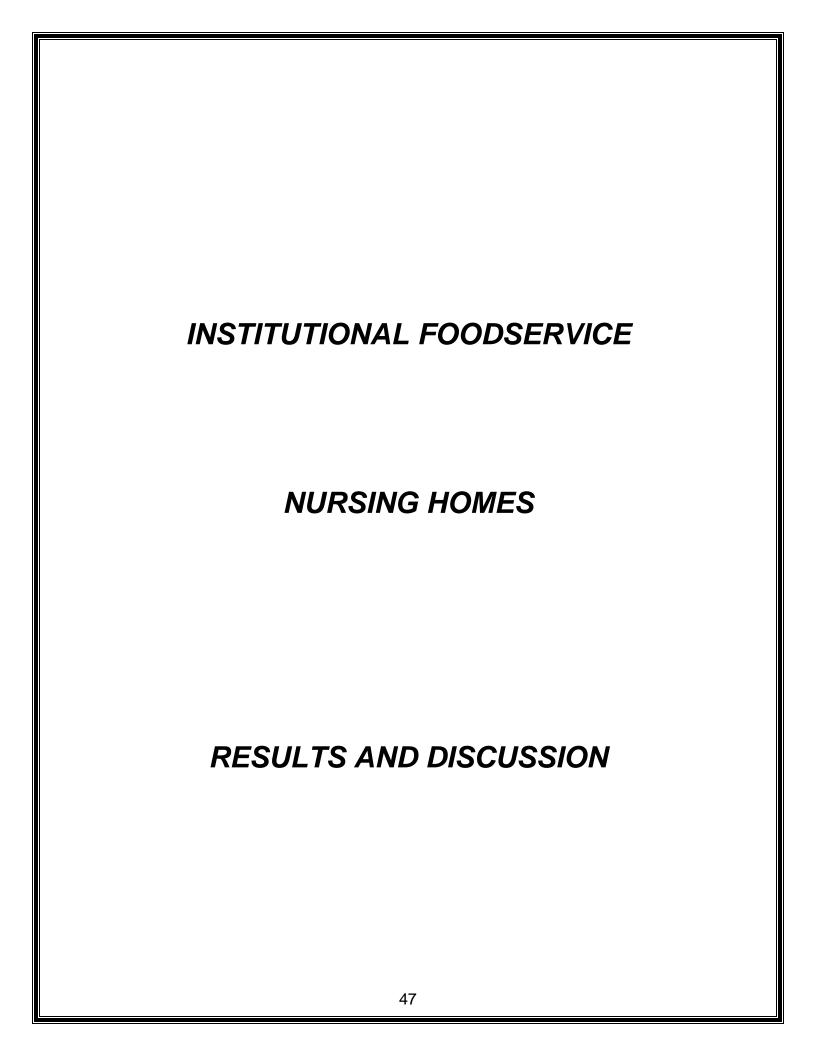
All of the Out of Compliance observations relating to the other/chemical risk factor are attributed to one data item. The proper identification, storage, and use of cleaners, sanitizers, and other chemicals in hospitals are in need of attention. Food safety procedures related to the identification, storage, 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 of this data item.

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

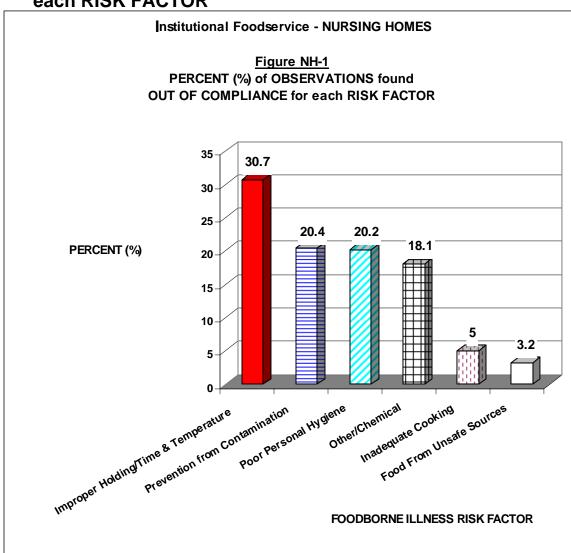
Table 11 Institutional Foodservice – HOSPITALS

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

DATA ITEMS IN Need of Priority Attention			
FOODBORNE ILLNESS	INDIVIDUAL DATA ITEM		
RISK FACTOR	in need of Priority Attention		
in need of Priority Attention	(From Section B)		
(From Section A)	, ,		
	PHF cooled to 70 °F in 2 hours/41 °F in total of 6		
	hours		
	PHF held cold at 41 °F or below		
Improper Holding/	Commercially-processed RTE, PHF date marked		
Time & Temperature			
·	RTE PHF date marked after 24 hours		
	PHF (prepared from ingredients at ambient		
	temperature) cooled to 41 °F or below within 4 hou		
	RTE, PHF discarded after 4 days/45 °F or		
	7 days/41 °F		
Contaminated Equipment/	Surface/Utensils cleaned/sanitized		
Protection from	Raw animal foods separated from RTE foods		
Contamination	Raw animal foods separated from each other		
Poor Personal Hygiene	Proper, adequate handwashing		
	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	# OUT	Total Obs (IN & OUT)	% OUT
Improper Holding/Time & Temperature	142	463	30.7%
Contaminated Equipment/Protection from Contamination	86	421	20.4%
Poor Personal Hygiene	91	450	20.2%
Other/Chemical	21	116	18.1%
Inadequate Cooking	8	161	5.0%
Food From Unsafe Sources	6	190	3.2%

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 when compared to the other risk factors evaluated during this data collection period.

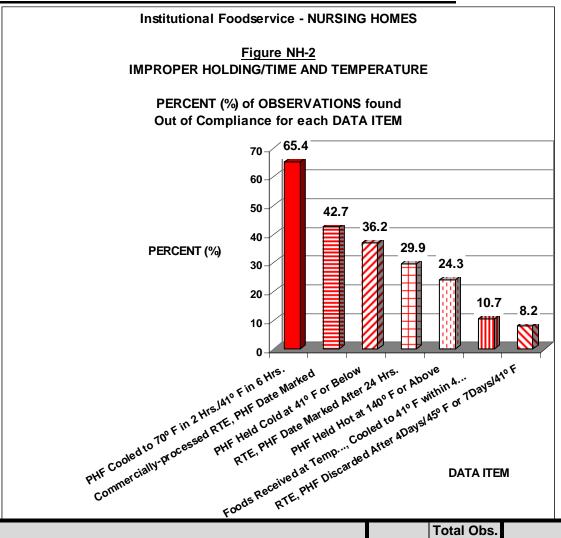
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

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

- Improper Holding/Time and Temperature (30.7%)
- Contaminated Equipment/Protection from Contamination (20.4%)
- Poor Personal Hygiene (20.2%)
- Other/Chemical (18.1%)

Figures NH-2 thru NH-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 nursing homes to control each of the risk factors during the 2003 data collection.

In general, the other/chemical risk factor had a high IN Compliance percentage. There was, however, one data item within this risk factor 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 will be presented.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	PHF cooled to 70 °F in 2 hours/41 °F in total of 6 hours	17	26	65.4%
	Commercially-processed, RTE, PHF date marked	32	75	42.7%
	PHF held cold at 41 °F or below	34	94	36.2%
	RTE, PHF date marked after 24 hours	26	87	29.9%
	PHF held hot at 140 °F or above	17	70	24.3%
	Foods received at temperatures according to Law are cooled to 41 °F within 4 hours.	3	28	10.7%
	RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F	5	61	8.2%
*	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F within 4 hours*	7*	14*	*
*	Roasts are held at temperature of 130 °F or above*	1*	6*	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0*	2*	*

^{*} These three remaining 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 potentially hazardous food (PHF) (65.4%)
- Date marking of open containers of commercially-processed ready-to-eat PHF (42.7%) and ready-to-eat PHF made on site (29.9%)
- Maintaining cold holding temperatures for PHF (36.2%)
- Maintaining hot holding temperatures for PHF (24.3%)

Cooling of PHF

Safe cooling requires the removal of heat from foods quickly enough to prevent the growth of spore-forming pathogens. Nursing home foodservice directors and managers need to ensure their practices and procedures are capable of rapidly cooling PHF.

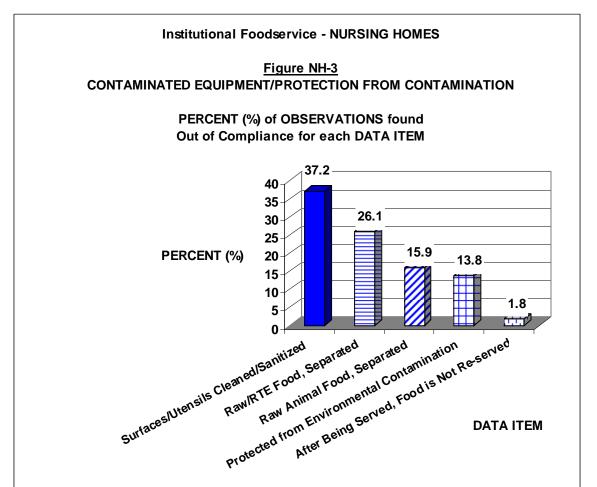
The total number of observations for cooling was substantially less than the total number of observations for other data items. The time of day the data was collected and the length of the time available to spend in a facility were significant factors limiting the number of observations of cooling. For example, as much as six hours may be required on site to document compliance with the *FDA Food Code* critical limits for cooling.

Date Marking

Date marking of refrigerated ready-to-eat, PHF is an important food safety system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF 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. The importance of date marking of ready-to-eat, PHF is accentuated in the nursing home environment because the meals are primarily served to a highly susceptible population.

Cold and Hot Holding of PHF

Holding PHF 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 need to be assessed and corrective action should be taken if necessary.



DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	35	94	37.2%
Raw/RTE foods, separated	23	88	26.1%
Raw animal food, separated	14	88	15.9%
Protected from environmental contamination	13	94	13.8%
After being served, food is not re-served	1	57	1.8%

Discussion for Figure NH-3

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

- Cleaning and sanitizing food contact surfaces and utensils (37.2%)
- Separating raw animal foods from ready-to-eat foods (26.1%)
- Separating raw animal foods (15.9%)

Cleaning and Sanitizing

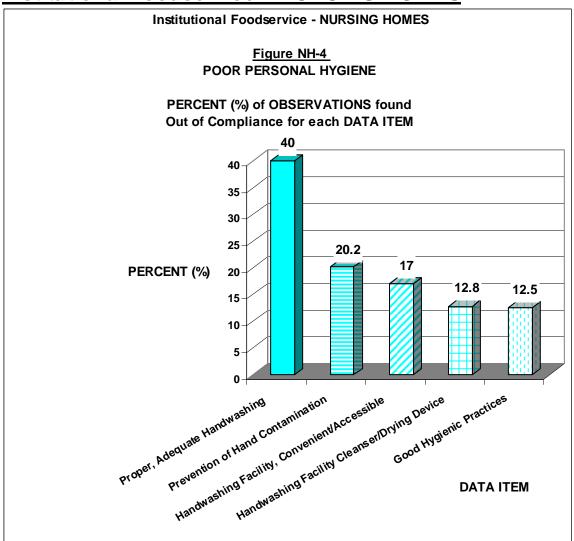
Proper cleaning and sanitization of food contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and stand-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 type of raw animal foods. Having organized storage systems that include designated areas for 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)	
Proper, adequate handwashing	34	85	40.0%
Prevention of hand contamination	18	89	20.2%
Handwashing facility, convenient/accessible	16	94	17.0%
Handwashing facility, cleanser/drying device	12	94	12.8%
Good hygienic practices	11	88	12.5%

Discussion for Figure NH-4

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

- Proper, adequate handwashing (40.0%)
- Prevention of hand contamination (20.2%)

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. 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 Hand Contamination

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 a major 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.

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

# Observations	TOTAL Observations	% Observations
OUT	(IN & OUT)	OUT
21	94	22.3%

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 is 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.

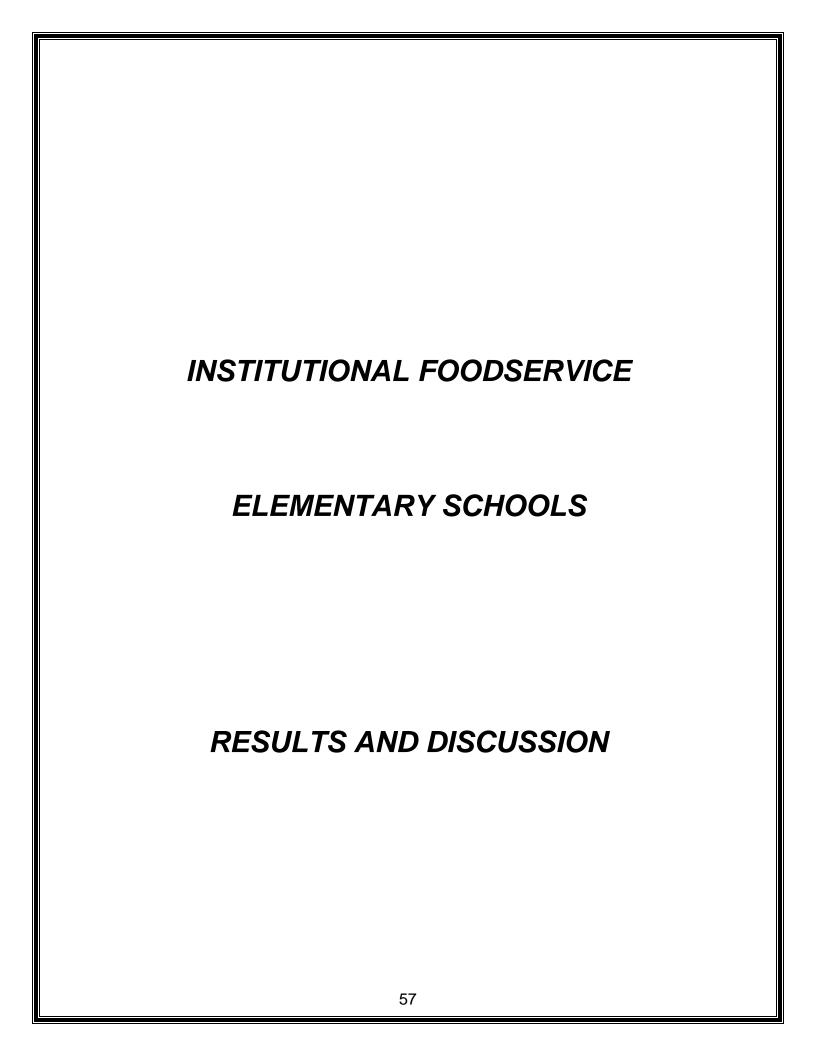
C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

Table 13

Institutional Foodservice - NURSING HOMES

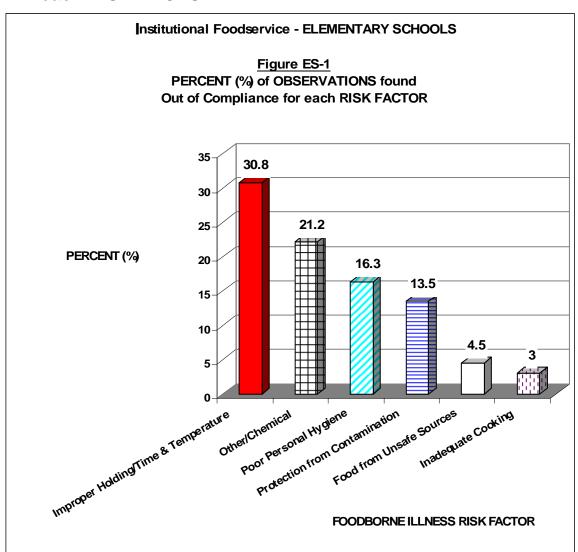
Summary of Foodborne Illness RISK FACTORS and DATA ITEMS in Need of Priority Attention

FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section B)		
(From Section A)		
	PHF cooled to 70 °F in 2 hours/41 °F in total of 6 hours	
Improper Holding/	Commercially-processed RTE, PHF date marked PHF held cold at 41 °F or below	
Time & Temperature	RTE PHF date marked after 24 hours	
	PHF held hot at 140 °F or above	
Contaminated Equipment/	Surface/Utensils cleaned/sanitized	
Protection from	Raw animal foods separated from RTE foods	
Contamination	Raw animal foods separated from each other	
Poor Personal Hygiene	Proper, adequate handwashing	
	Prevention of hand contamination	
Other/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		Total Obs. (IN & OUT)	% OUT
Improper Holding/Time & Temperature	118	383	30.8%
Other/Chemical	24	113	21.2%
Poor Personal Hygiene	78	478	16.3%
Contaminated Equipment/Protection from Contamination	46	340	13.5%
Food from Unsafe Sources	9	199	4.5%
Inadequate Cooking	3	99	3.0%

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

Discussion for Figure ES-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 when compared to the other risk factors evaluated during this data collection period.

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

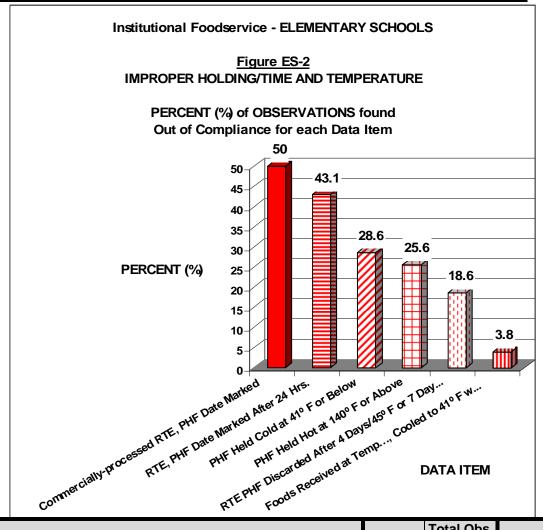
For elementary schools, the foodborne illness risk factors most in need of attention and their corresponding Out of Compliance percentages are:

- Improper Holding/Time and Temperature (30.8%)
- Other/Chemical (21.2%)
- Poor Personal Hygiene (16.3%)
- Contaminated Equipment/Protection from Contamination (13.5%)

Figures ES-2 thru ES-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 elementary schools to control each of the risk factors during the 2003 data collection.

The Out of Compliance percentage noted for the other/chemical risk factor was attributed to one specific 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 will be presented.

Institutional Foodservice - ELEMENTARY SCHOOLS



	DATA ITEM		Total Obs. (IN & OUT)	% OUT
	Commercially-processed, RTE, PHF date marked	32	64	50.0%
	RTE, PHF date marked after 24 hours	22	51	43.1%
	PHF held cold at 41 °F or below	28	98	28.6%
	PHF held hot at 140 °F or above	21	82	25.6%
	RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F	8	43	18.6%
	Foods received at temperatures according to Law are cooled to 41 °F within 4 hours.	1	26	3.8%
*	PHF cooled to 70 °F in 2 hours/41 °F in total of 6 hours *	5*	8*	*
*	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F or below within 4 hours*	1*	7*	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0*	4*	*
*	Roasts are held at a temperature of 130 °F or above*	0*	0*	*

^{*} These four remaining 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 systems related to:

- Date marking of open containers of commercially-processed, ready-to-eat PHF (50.0%) and ready-to eat, PHF made on site (43.1%)
- Maintaining cold holding temperatures for PHF (28.6%)
- Maintaining hot holding temperatures for PHF (25.6%)

Date Marking

Date marking of refrigerated ready-to-eat, PHF is an important food safety system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF 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. The importance of date marking of ready-to-eat, PHF is accentuated in elementary schools because the meals are primarily served to a highly susceptible population.

Cold and Hot Holding of PHF

Holding PHF 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 need to be assessed and corrective action should be taken if necessary.

Discussion for the Other/Chemical Risk Factor

Table 14

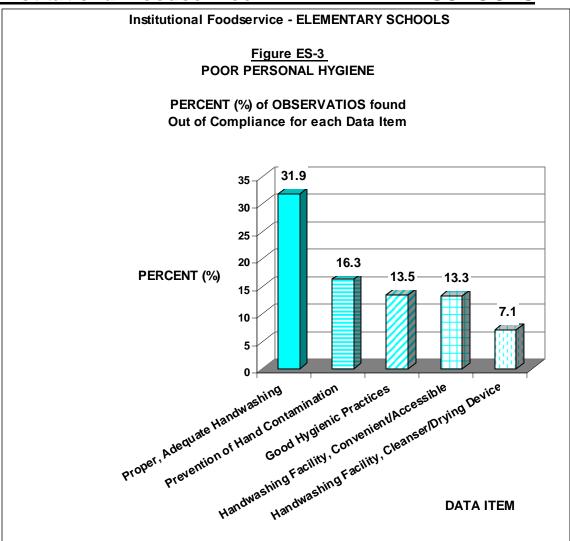
Assessment of the Other/Chemical Category – ELEMENTARY SCHOOLS

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

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
24	98	24.5%

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 is 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



DATA ITEM		# OUT	Total Obs. (IN & OUT)	% OUT
	Proper, adequate handwashing	30	94	31.9%
	Prevention of hand contamination	15	92	16.3%
	Good hygienic practices	13	96	13.5%
	Handwashing facility, convenient/accessible	13	98	13.3%
	Handwashing facility, cleanser/drying device	7	98	7.1%

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

Discussion for Figure ES-3

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

- Proper, adequate handwashing (31.9%)
- Prevention of hand contamination (16.3%)

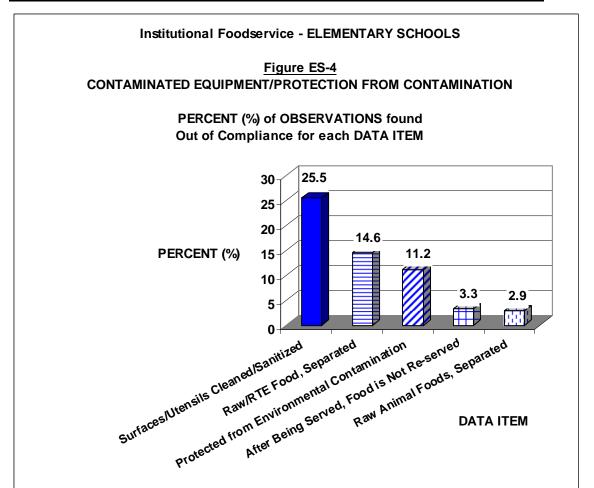
Proper, Adequate Handwashing

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. 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 Hand Contamination

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 a major 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.

Institutional Foodservice - ELEMENTARY SCHOOLS



		Total Obs.	
DATA ITEM		(IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	25	98	25.5%
Raw/RTE foods, separated	7	48	14.6%
Protected from environmental contamination	11	98	11.2%
After being served, food is not e-served	2	61	3.3%
Raw animal foods, separated	1	35	2.9%

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

Discussion for Figure ES-4

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

- Cleaning and sanitizing food contact surfaces and utensils (25.5%)
- Separating raw animal foods from ready-to-eat foods (14.6%)

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 stand-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 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 type of raw animal foods. Having organized storage systems that include designated areas for 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.

Institutional Foodservice - ELEMENTARY SCHOOLS

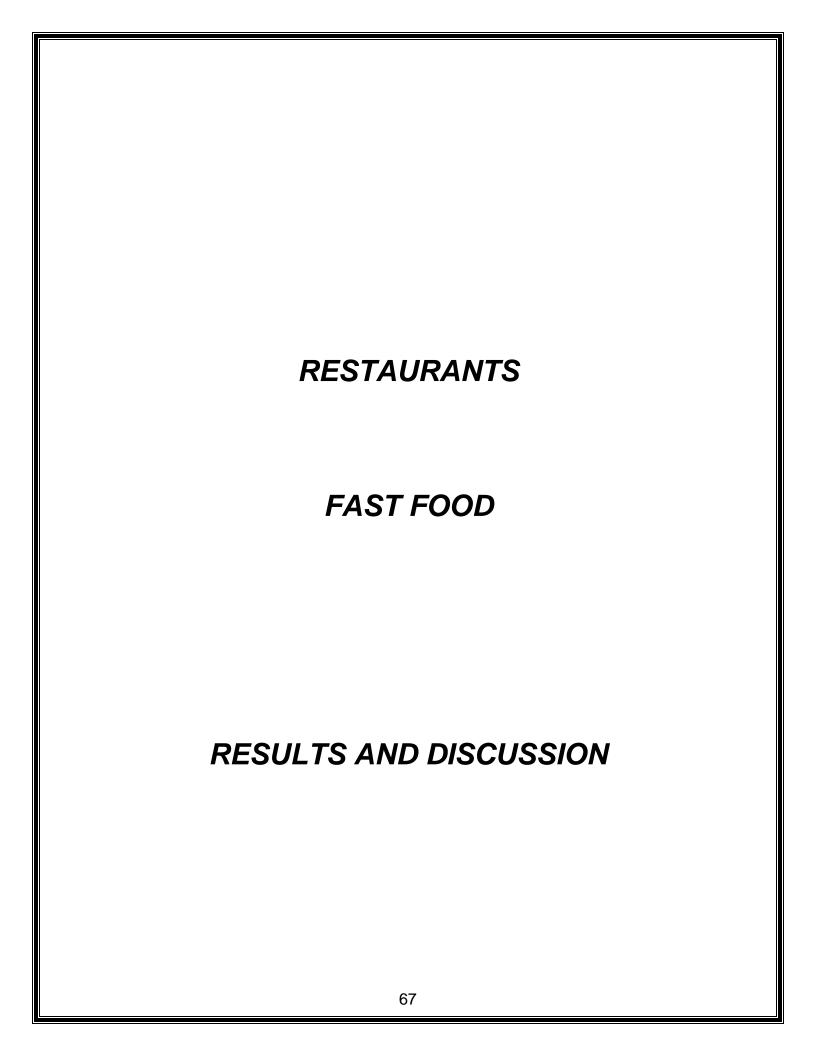
C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

Table 15

Institutional Foodservice - ELEMENTARY SCHOOLS

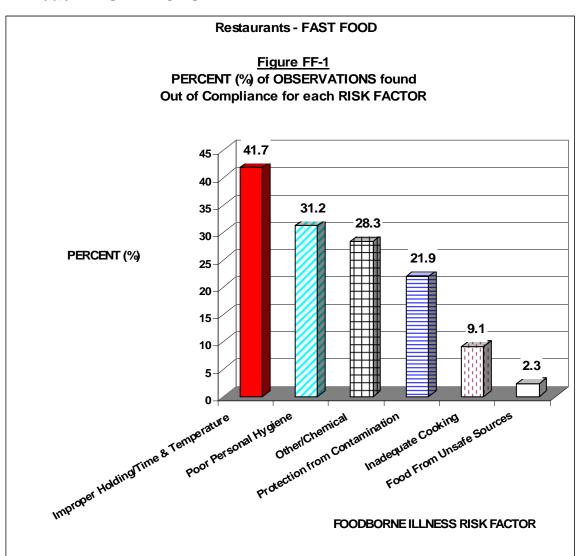
Summary of Foodborne Illness RISK FACOTRS and DATA ITEMS in Need of Priority Attention

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 date marked RTE, PHF date marked after 24 hours PHF held cold at 41 °F or below PHF held hot 140 °F or above RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F
Other/Chemical	Poisonous or toxic materials properly identified, stored, and used
Poor Personal Hygiene	Proper, adequate handwashing Prevention of hand contamination
Contaminated Equipment/ Protection from Contamination	Surfaces/Utensils cleaned/sanitized Raw animal food separated from ready-to-eat foods



Restaurants - FAST FOOD

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	180	432	41.7%
Poor Personal Hygiene	165	529	31.2%
Other/Chemical	34	120	28.3%
Contaminated Equipment/Protection from Contamination	95	434	21.9%
Inadequate Cooking	17	186	9.1%
Food From Unsafe Sources	5	216	2.3%

Discussion for Figure FF-1

Failure to control product holding temperatures and times was the risk factor with the highest Out of Compliance percentage. Poor personal hygiene, chemical contamination, 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 when compared to the other risk factors evaluated during this data collection period.

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

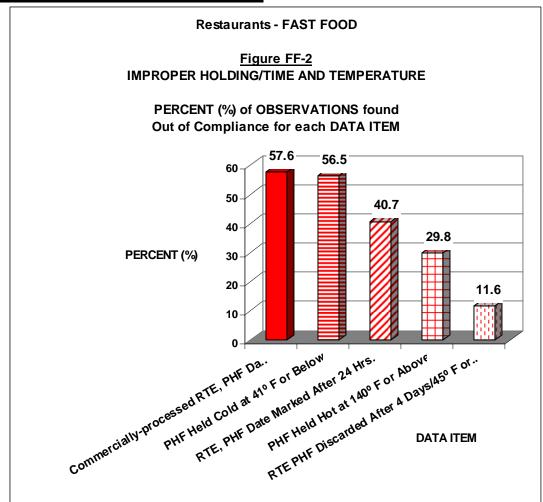
For fast food restaurants, the foodborne illness risk factors most in need of attention and their corresponding Out of Compliance percentages are:

- Improper Holding/Time and Temperature (41.7%)
- Poor Personal Hygiene (31.2%)
- Other/Chemical (28.3%)
- Contaminated Equipment/Protection from Contamination (21.9%)

Figures FF-2 thru FF-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 fast food restaurants to control each of the risk factors during the 2003 data collection.

The Out of Compliance percentage noted for the other/chemical risk factor was attributed to one specific 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 will be presented.

In addition, the inadequate cooking risk factor had one data item of interest. The results for cooking comminuted fish/meat/game animals will also be presented.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	Commercially-processed, RTE, PHF date marked	38	66	57.6%
	PHF held cold at 41 °F or below	61	108	56.5%
	RTE, PHF date marked after 24 hours	24	59	40.7%
	PHF held hot at 140 °F or above	28	94	29.8%
	RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F	5	43	11.6%
*	When time only is used as a public health control, food is cooked and served within 4 hours*	4*	18*	*
*	Foods received at temperatures according to Law are cooled to 41 °F within 4 hours.	2*	14*	*
*	PHF cooled to 70 °F in 2 hours/41 °F in total of 6 hours*	10*	12*	*
*	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F or below within 4 hours*	5*	12*	*
*	Roasts are held at a temperature of 130 °F or above	3*	6*	*

^{*} These five remaining 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:

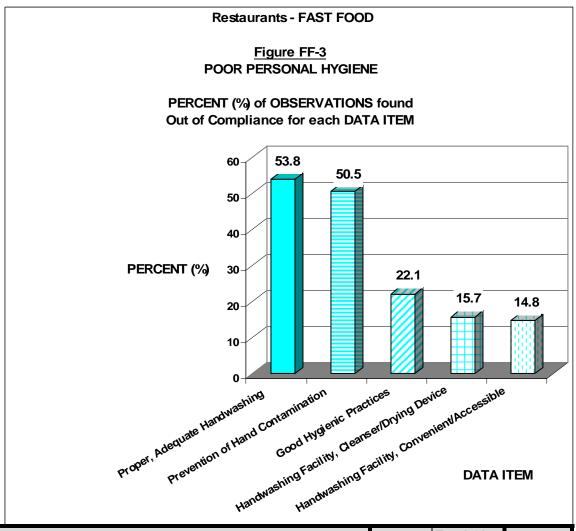
- Date marking of open containers of commercially-processed, ready-to-eat PHF (57.6%) and ready-to eat, PHF made on site (40.7%)
- Maintaining cold holding temperatures for PHF (56.5%)
- Maintaining hot holding temperatures for PHF (29.8%)

Date Marking

Date marking of refrigerated ready-to-eat, PHF is an important food safety system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF 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

Holding PHF 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 need to be assessed and corrective action should be taken if necessary.



DATA ITEM		Total Obs. (IN & OUT)	
Proper, adequate handwashing	56	104	53.8%
Prevention of hand contamination	53	105	50.5%
Good hygienic practices	23	104	22.1%
Handwashing facility, cleanser/drying device	17	108	15.7%
Handwashing facility, convenient/accessible	16	108	14.8%

Discussion for Figure FF-3

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

- Proper, adequate handwashing (53.8%)
- Prevention of hand contamination (50.5%)
- Good hygienic practices (22.1%)

Proper, Adequate Handwashing

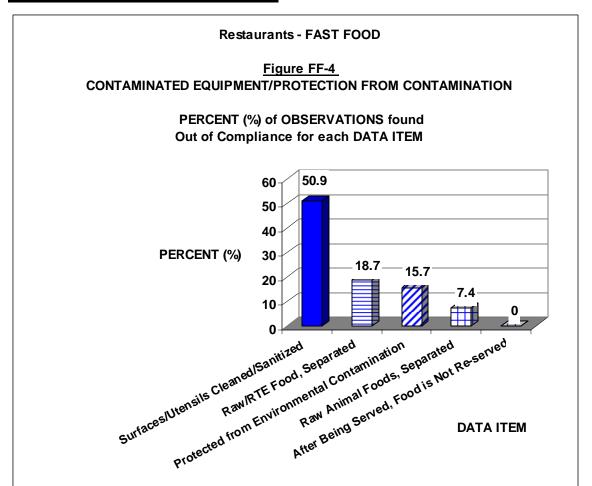
Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures 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. 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 Hand Contamination

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 a major 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		Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	55	108	50.9%
Raw/RTE foods, separated	17	91	18.7%
Protected from environmental contamination	17	108	15.7%
Raw animal foods, separated	6	81	7.4%
After being served, food is not re-served	0	46	0.0%

Discussion for Figure FF-4

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

- Cleaning and sanitizing food contact surfaces and utensils (50.9%)
- Separating raw animal foods from ready-to-eat foods (18.7%)

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 stand-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.

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. Having organized storage systems that include designated areas for 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.

Discussion for the Other/Chemical Risk Factor

Table 15

Assessment of the Other/Chemical Category – FAST FOOD RESTAURANTS

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

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
34	108	31.5%

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 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.

Discussion for the Inadequate Cooking Risk Factor

Table 16

Assessment of the Inadequate Cooking Risk Factor FAST FOOD RESTAURANTS

Comminuted Fish/Meats/Game Animals Cooked to 155 °F/15 seconds

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
8	50	16.0%

Cooking foods to temperatures that destroy pathogens is critical to reducing the risk of foodborne illness. 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.

Of the fast food restaurants observed to be cooking comminuted (ground) meat/fish/game animals, 16% of these were found to be Out of Compliance. The large number of servings of these foods, prepared and sold by fast food restaurants, suggest that reducing the Out of Compliance percentage for this data item is an important public health concern.

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

Table 17

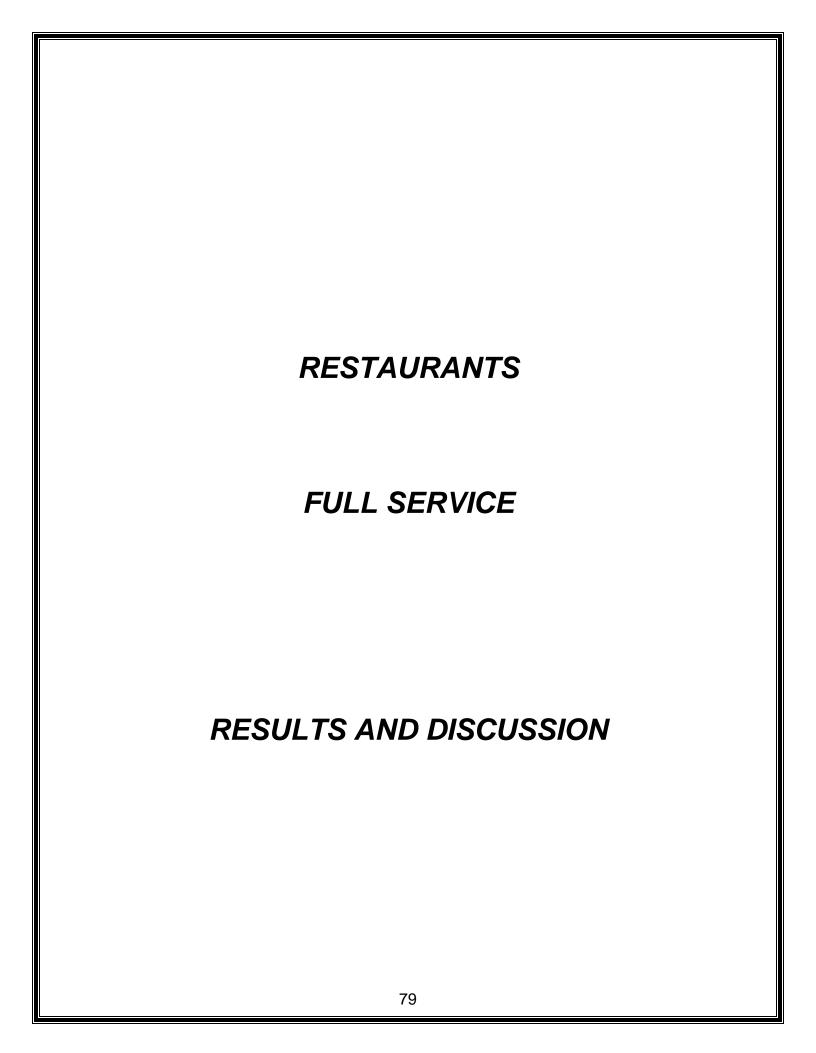
Restaurants – FAST FOOD

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

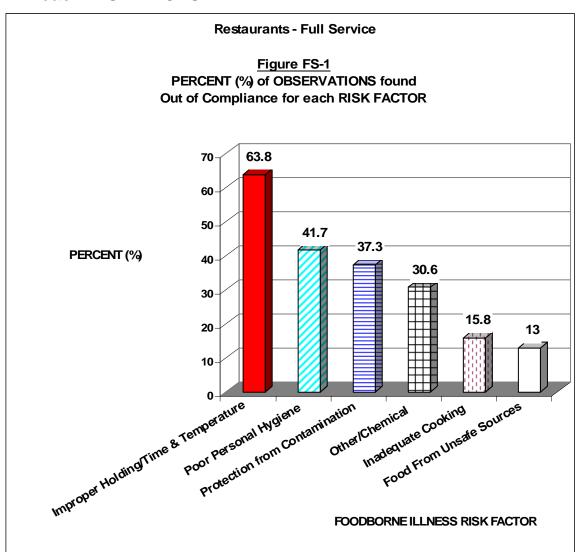
FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)
Improper Holding/ Time & Temperature	Commercially-processed RTE, PHF date marked PHF held cold at 41 °F or below RTE, PHF date marked after 24 hours PHF held hot at 140 °F or above
Poor Personal Hygiene	Proper, adequate handwashing Prevention of hand contamination Good hygienic practices
Other/Chemical	Poisonous or toxic materials properly identified, store, and used
Contaminated Equipment/ Protection from Contamination	Surfaces/Utensils cleaned/sanitized Raw animal food separated from ready-to-eat foods
Inadequate Cooking	Comminuted fish/meat/game animals cooked to 155 °F/15 seconds

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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	300	470	63.8%
Poor Personal Hygiene	203	487	41.7%
Contaminated Equipment/Protection from Contamination	163	437	37.3%
Other/Chemical	38	124	30.6%
Inadequate Cooking	38	240	15.8%
Food From Unsafe Sources	33	254	13.0%

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, 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 when compared to the other risk factors evaluated during this data collection period.

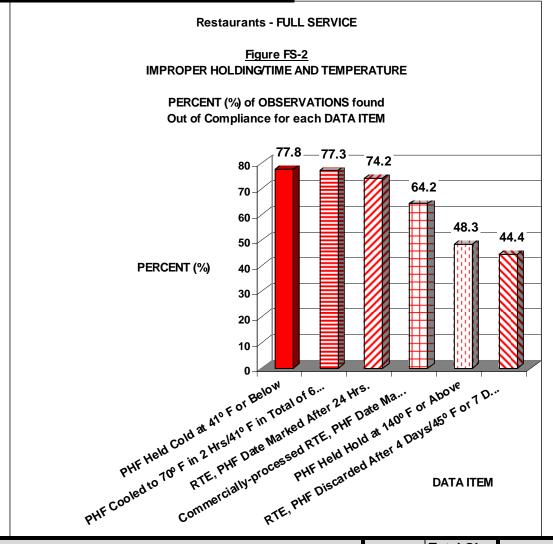
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

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

- Improper Holding/Time Temperature (63.8%)
- Poor Personal Hygiene (41.7%)
- Contaminated Equipment/Protection from Contamination (37.3%)
- Other/Chemical (30.6%)

Figures FS-2 thru FS-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 full service restaurants to control each of the risk factors during the 2003 data collection.

The other/chemical, inadequate cooling, and food from unsafe sources risk factors all had high IN Compliance percentages. There were, however, a few data items within each of these risk factors that are in need of attention. Information for these data items will be presented as part of the discussion.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	PHF held cold at 41 °F or below	77	99	77.8%
	PHF cooled to 70 °F in 2 hours/41 °F in total of 6 hours	34	44	77.3%
	RTE, PHF date marked after 24 hours	69	93	74.2%
	Commercially-processed, RTE, PHF date marked	43	67	64.2%
	PHF held hot at 140 °F or above	42	87	48.3%
	RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F	16	36	44.4%
*	Foods received at temperatures according to Law are cooled to 41 °F within 4 hours.*	6*	18*	*
*	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F or below within 4 hours*	7*	16*	*
*	Roasts are held at a temperature of 130 °F or above*	3*	5*	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	3*	5*	*

^{*} These four remaining 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:

- Maintaining cold holding temperatures for PHF (77.8%)
- Cooling of PHF (77.3%)
- Date marking of ready-to eat, PHF made on-site (74.2%) and open containers of commercially-processed, ready-to-eat PHF (64.2%)
- Maintaining hot holding temperatures for PHF (48.3.9%)
- Discarding RTE, PHF after they have exceeded time/temperature storage limits (44.4%)

Cold and Hot Holding of PHF

Holding PHF 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 need to be assessed and corrective action should be taken if necessary.

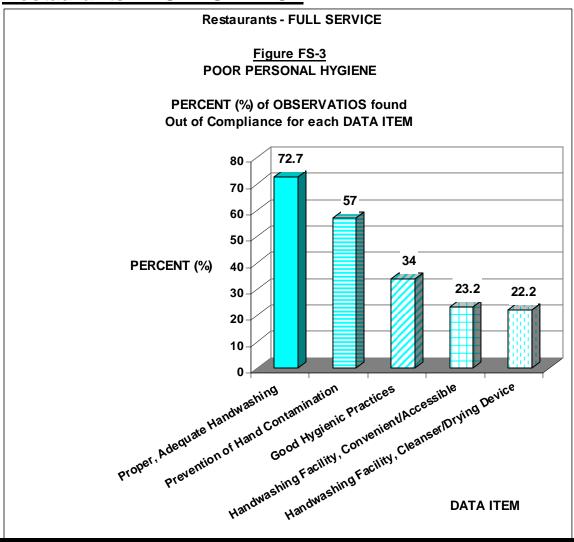
Cooling of PHF

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

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 *Food Code* critical limits for cooling.

Date Marking

Date marking of refrigerated ready-to-eat, PHF, such as deli meats, meat or seafood salads, and soft cheeses, is an important food safety system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF foods 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.



		Total Obs.	
DATA ITEM	# OUT	(IN & OUT)	% OUT
Proper, adequate handwashing	72	99	72.7%
Prevention of hand contamination	53	93	57.0%
Good hygienic practices	33	97	34.0%
Handwashing facility, convenient/accessible	23	99	23.2%
Handwashing facility, cleanser/drying device	22	99	22.2%

Discussion for Figure FS-3

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

- Proper, adequate handwashing (72.7%)
- Prevention of hand contamination (57.0%)
- Good hygienic practices (34.0%)
- Handwashing facility, convenient/accessible (23.2%)
- Handwashing facility, cleanser/drying device (22.2%)

Proper, Adequate Handwashing

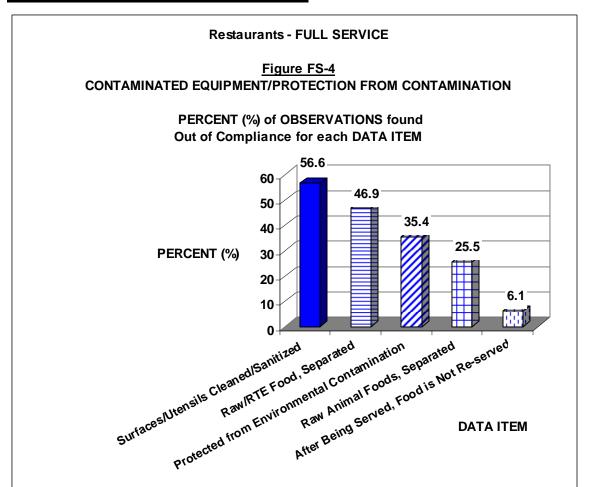
Hands may become contaminated when employees engage in activities such as handling raw animal foods, using the restroom or handling soiled tableware. Hands are a common vehicle for the transfer of harmful bacteria and viruses to food products. Effective handwashing is one of the most important measures to minimize the contamination of food by employees. The lack of convenient handwashing facilities or supplies of hand cleanser/drying devices may contribute to a lack of proper 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 Hand Contamination

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 a major 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		Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	56	99	56.6%
Raw/RTE foods, separated	45	96	46.9%
Protected from environmental contamination	35	99	35.4%
Raw animal foods, separated	24	94	25.5%
After being served, food is not re-served	3	49	6.1%

Discussion for FS-4

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

- Cleaning and sanitizing food contact surfaces and utensils (56.6%)
- Separating raw animal foods from ready-to-eat foods (46.9%)
- Protection from environmental contamination (35.4%)
- Separating raw animal foods (25.5%)

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 stand-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 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. Having organized storage systems that include designated areas for 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.

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 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 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

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
38	99	38.4%

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 foods to temperatures that destroy pathogens is critical to reducing the risk of foodborne illness. 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.

Cooking of poultry and stuffed food products

Table 19

Assessment of the Inadequate Cooking Risk Factor FULL SERVICE RESTAURANTS

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

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
9	47	19.2%

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 *Salmonellae* 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 19% were found to be Out of Compliance with this important food safety requirement.

Reheating of PHF

Table 20

Assessment of the Inadequate Cooking Risk Factor FULL SERVICE RESTAURANTS

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

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
11	36	30.6%

It is important to properly reheat PHF that was initially cooked and cooled on premises and which 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 for hot holding was observed, approximately 31% were found to be Out of Compliance.

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

Table 21

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

Shellstock Tags Retained for 90 Days

# Observations	TOTAL Observations	% Observations
OUT	(IN & OUT)	OUT
13	19	68.4%

The overall IN Compliance percentage for 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 nineteen total observations. Of the observations made, thirteen 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 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 should a food-related illness or contamination be associated with shellstock.

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

Table 22

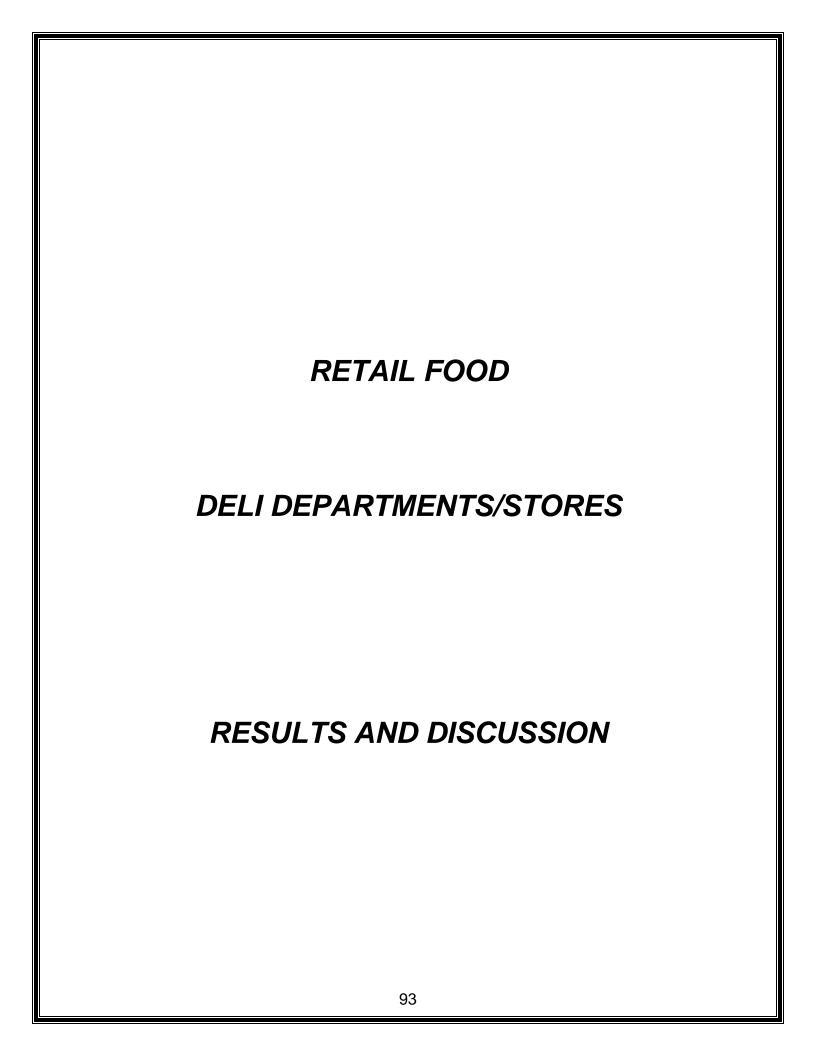
Restaurants – FULL SERVICE

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

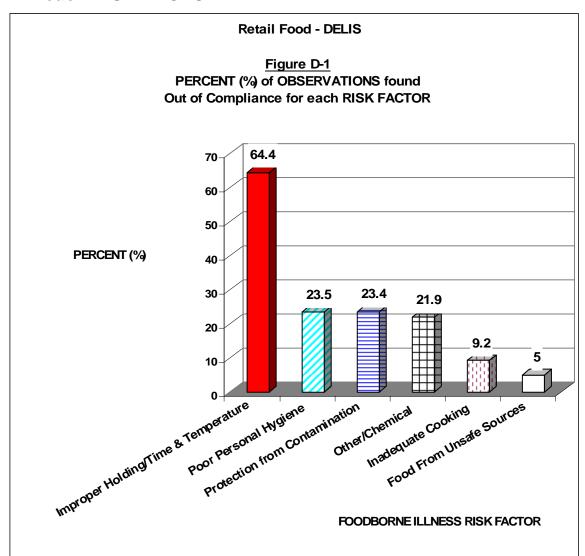
DATATIL	MS in Need of Priority Attention
FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)
Improper Holding/ Time & Temperature	PHF held cold at 41 °F or below PHF cooled to 70 °F in 2 hours/41 °F in total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

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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	315	489	64.4%
Poor Personal Hygiene	124	528	23.5%
Contaminated Equipment/Protection from Contamination	102	435	23.4%
Other/Chemical	30	137	21.9%
Inadequate Cooking	14	153	9.2%
Food From Unsafe Sources	11	221	5.0%

Discussion for Figure D-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 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 when compared to the other risk factors evaluated during this data collection period.

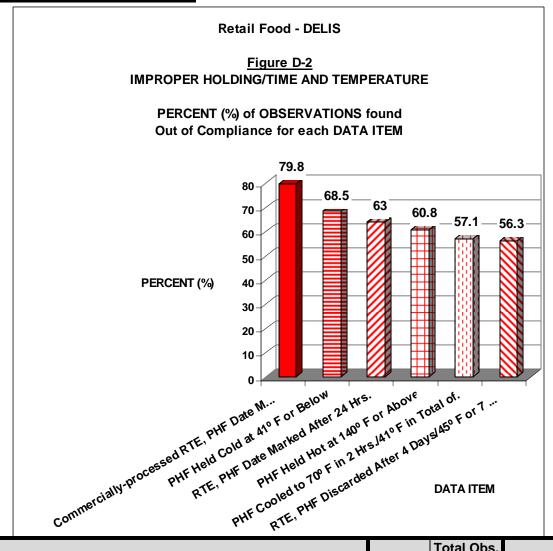
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

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

- Improper Holding/Time and Temperature (64.4%)
- Poor Personal Hygiene (23.5%)
- Contaminated Equipment/Protection from Contamination (23.4%)
- Other/Chemical (21.9%)

Figures D-2 thru D-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 delis to control each of the risk factors during the 2003 data collection.

In general, the other/chemical risk factor had a high IN Compliance percentage. There was, however, one data item within this risk factor 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 will be presented.



DATA ITEM		# OUT	Total Obs. (IN & OUT)	% OUT
	Commercially-processed, RTE, PHF date marked	79	99	79.8%
	PHF held cold at 41 °F or below	74	108	68.5%
	RTE, PHF date marked after 24 hours	51	81	63.0%
	PHF held hot at 140 °F or above	59	97	60.8%
	PHF cooled to 70 °F on 2 hours/41 °F in total of 6 hours	16	28	57.1%
	RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F	27	48	56.3%
*	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F or below within 4 hours *	6*	13*	*
*	Foods received at temperatures according to Law are cooled to 41 °F within 4 hours.*	1*	9*	*
*	Roasts are held at a temperature of 130 °F or above*	2*	4*	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0*	2*	*

^{*} These four remaining 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 food safety systems related to:

- Date marking of open containers of commercially-processed, ready-to-eat, PHF (79.8%) and ready-to eat, PHF made on site (63.0%)
- Maintaining cold holding temperatures for PHF (68.5%)
- Maintaining hot holding temperatures for PHF (60.8%)
- Cooling of PHF (57.1%)

Date Marking

Date marking of refrigerated ready-to-eat, PHF, such as deli meats, meat salads, and soft cheeses, is an important food safety system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF 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.

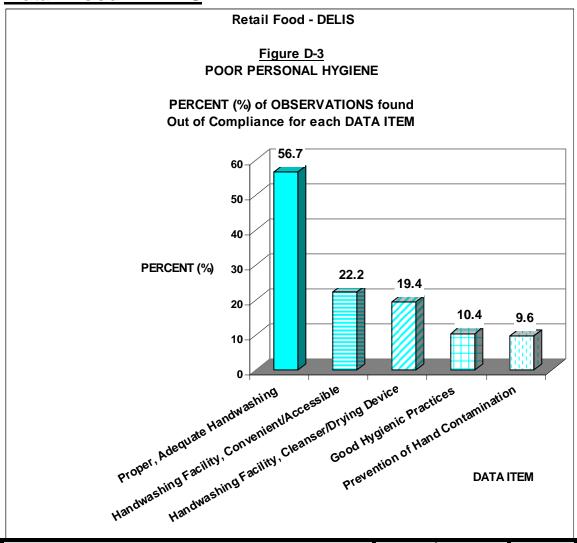
Cold and Hot Holding of PHF

Holding PHF at the proper cold and hot temperatures is critical to preventing the growth of bacteria. Equipment, processes, and monitoring procedures related to maintaining temperature control for PHF need to be assessed and corrective action should be taken if necessary.

Cooling of PHF

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.

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 *Food Code* critical limits for cooling.



		Total Obs.	
DATA ITEM		(IN & OUT)	% OUT
Proper, adequate handwashing	58	102	56.9%
Handwashing facility, convenient/accessible	24	108	22.2%
Handwashing facility, cleanser/drying device	21	108	19.4%
Good hygienic practices	11	106	10.4%
Prevention of hand contamination	10	104	9.6%

Discussion for Figure D-3

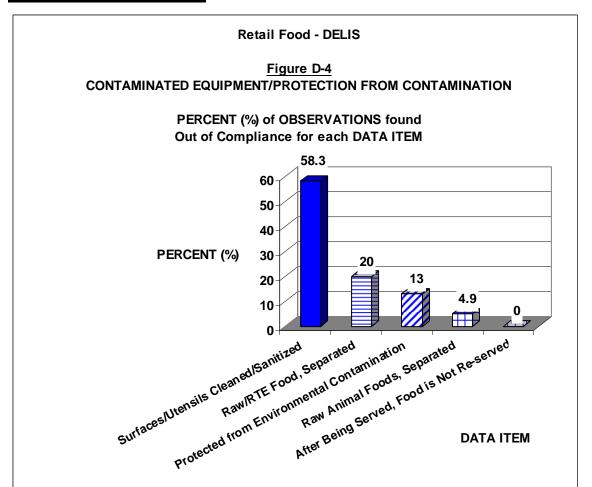
The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include:

- Proper, adequate handwashing (56.9%)
- Handwashing facility, convenient/accessible (22.2%)
- Handwashing facility, cleanser/drying device (19.4%)

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 the lack of proper 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 2003 study show a relatively high IN Compliance percentage (90.4%) for preventing direct hand contamination with food in delis. The retail food management in delis appear to be making a concerted effort to eliminate bare hand contact with ready-to-eat foods.



		Total Obs.	
DATA ITEM	# OUT	(IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	63	108	58.3%
Raw/RTE foods separated	21	105	20.0%
Protected from environmental contamination	14	108	13.0%
Raw animal foods, separated	4	82	4.9%
After being served, food is not re-served	0	32	0.0%

Discussion for Figure D-4

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

- Cleaning and sanitizing food contact surfaces and utensils (58.3%)
- Separating raw animal foods from ready-to-eat foods (20.0%)

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 stand-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 type of raw animal foods. Having organized storage systems that include designated areas for 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.

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

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
30	108	27.8%

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 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.

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

Table 24

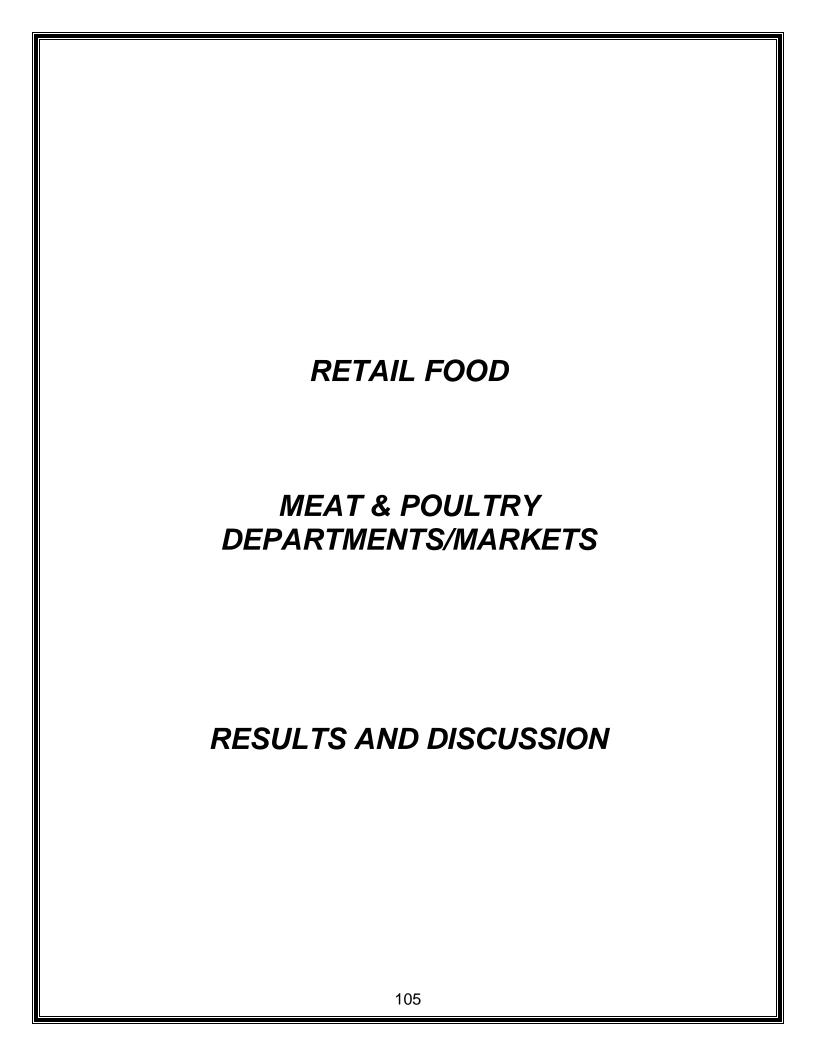
Retail Food Store – DELIS

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

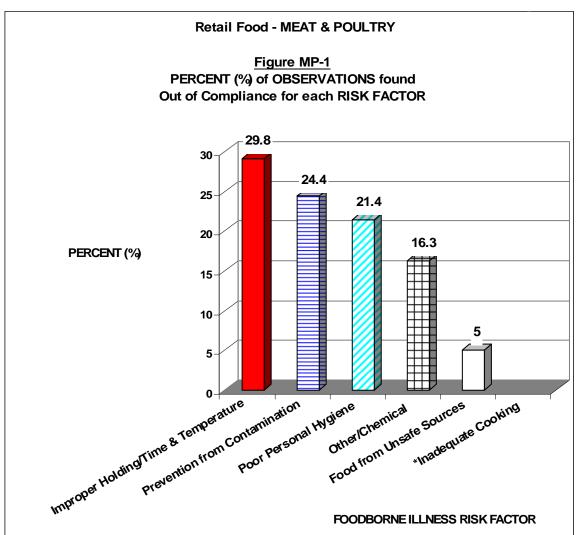
FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS In need of Priority Attention (From Section B)
Improper Holding/ Time & Temperature	Commercially-processed RTE, PHF date marked PHF held cold at 41 °F or below RTE, PHF date marked after 24 hours PHF held hot at 140 °F or above PHF cooled to 70 °F in 2 hours/41 °F in total of 6 hours RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F
Poor Personal Hygiene	Proper, adequate handwashing Handwashing facility, convenient/accessible Handwashing facility, cleanser/drying device
Contaminated Equipment/ Protection from Contamination	Surfaces/Utensils cleaned/sanitized Raw animal food separated from ready-to-eat foods
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)	% OUT
	Improper Holding/Time & Temperature	48	161	29.8%
	Contaminated Equipment/Protection from Contamination	107	438	24.4%
	Poor Personal Hygiene	91	425	21.4%
	Other/Chemical	20	123	16.3%
	Food from Unsafe Sources	12	242	5.0%
*	Inadequate Cooking*	1*	2*	*

^{*} 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, 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 when compared to the other risk factors evaluated during this data collection period.

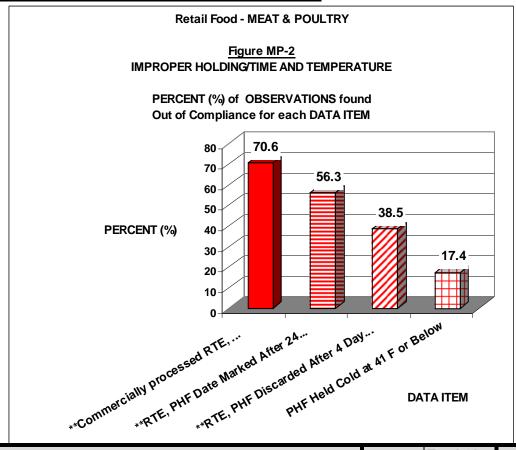
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

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

- Improper Holding/Time Temperature (29.8%)
- Contaminated Equipment/Protection from Contamination (24.4%)
- Poor Personal Hygiene (21.4%)
- Other/Chemical (16.3%)

Figures MP-2 thru MP-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 meat and poultry department to control each of the risk factors during the 2003 data collection.

In general, the other/chemical risk factor had a high IN Compliance percentage. There was, however, one data item within this risk factor 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 will be presented.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
**	Commercially-processed, RTE, PHF date marked**	12**	17**	70.6%**
**	RTE, PHF date marked after 24 hours**	9**	16**	56.3%**
**	RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F**	5**	13**	38.5%**
	PHF held cold at 41 °F or below	19	109	17.4%
*	PHF held hot at 140 °F or above*	2*	2*	*
*	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F or below within 4 Hours*	0*	2*	*
*	PHF cooled to 70 °F in 2 hours/41 °F in total of 6 hours*	1*	1*	*
*	Foods received at temperatures according to Law are cooled to 41 °F within 4 hours.*	0*	1*	*
*	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 remaining Improper Holding/Time & Temperature Data Items do not appear in Figure MP-2 due to a low number of total observations (obs.)

^{**}These three data items are included in Figure MP-2 even though each has less than twenty 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 systems related to:

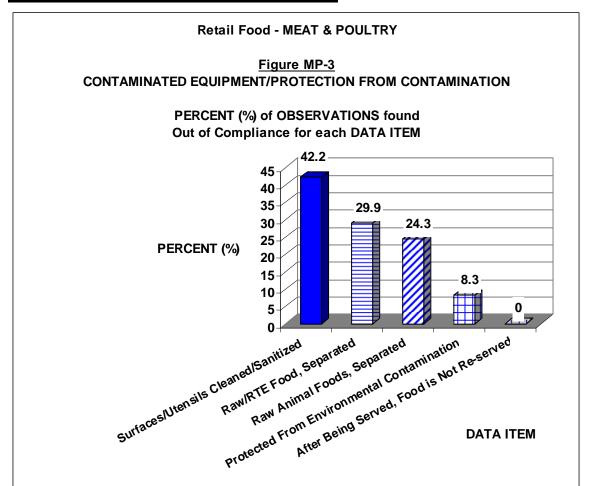
- Date marking of open containers of commercially-processed, ready-to-eat, PHF (70.6%) and ready-to eat, PHF made on site (56.3%)
- Maintaining cold holding temperatures for PHF (17.4%)

Date Marking

Date marking of refrigerated ready-to-eat, PHF, such as salads containing various meats that may be prepared or sold, is an important food safety system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF 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 Holding of PHF

Holding PHF 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 need to be assessed and corrective action should be taken if necessary.



DATA ITEM		Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	46	109	42.2%
Raw/RTE foods, separated	26	87	29.9%
Raw animal foods, separated	26	107	24.3%
Protected from environmental contamination	9	109	8.3%
After being served, food is not re-served	0	26	0.0%

Discussion for Figure MP-3

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

- Cleaning and sanitizing food contact surfaces and utensils (42.2%)
- Separating raw animal foods from ready-to-eat foods (29.9%)
- Separating raw animal foods from each other (24.3%)

Cleaning and Sanitizing

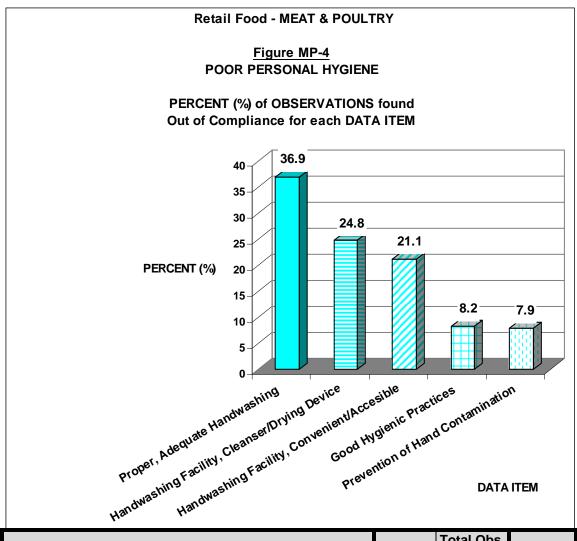
Proper cleaning and sanitization of food contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and stand-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 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. Having organized storage systems that include designated areas for 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		Total Obs. (IN & OUT)	% OUT
Proper, adequate handwashing	31	84	36.9%
Handwashing facility, cleanser/drying device	27	109	24.8%
Handwashing facility, convenient/accessible	23	109	21.1%
Good hygienic practices	7	85	8.2%
Prevention of hand contamination	3	38	7.9%

Discussion for Figure MP-4

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

- Proper, adequate handwashing (36.9%)
- Handwashing facility, cleanser/drying device (24.8%)
- Handwashing facility, convenient/accessible (21.1%)

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 the lack of proper 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 2003 study show a high IN Compliance percentage (92.1%) for preventing direct hand contamination with food in meat and poultry departments. The retail food management in meat and poultry 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 25

Assessment of the Other/Chemical Category – MEAT AND POULTRY

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

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
19	109	17.4%

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.

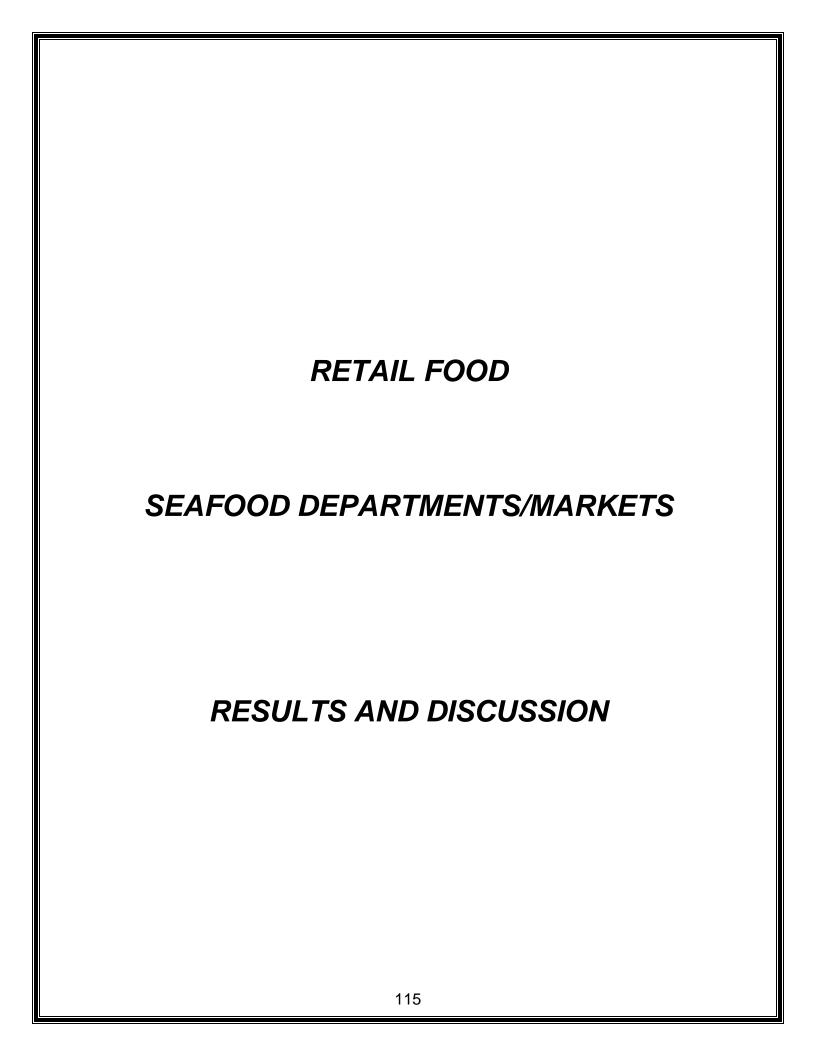
C. Summary of foodborne illness RISK FACTORS and INDIVIDUAL DATA ITEMS in need of priority attention

Table 26

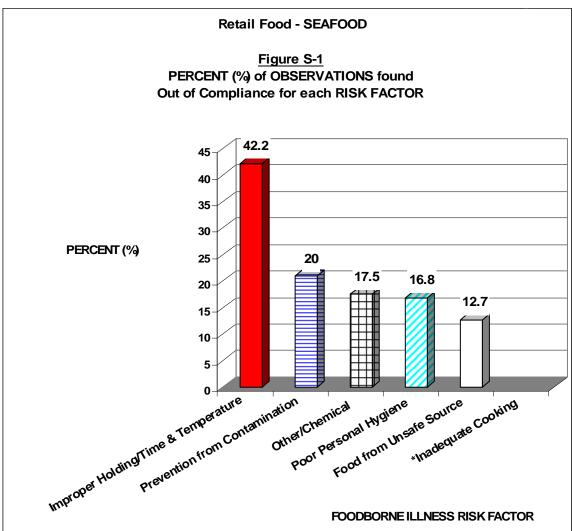
Retail Food Store - MEAT AND POULTRY

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	Commercially-processed RTE, PHF date marked RTE, PHF date marked after 24 hours RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F PHF held cold at 41 °F or below
Contaminated Equipment/ Protection from Contamination	Surfaces/Utensils cleaned/sanitized Raw animal food separated from ready-to-eat foods
Poor Personal Hygiene	Proper, adequate handwashing Handwashing facility, cleanser/drying device Handwashing facility, convenient/accessible
Other/Chemical	Poisonous or toxic materials properly identified, stored, and used



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	95	225	42.2%
	Contaminated Equipment/Protection from Contamination	84	419	20.0%
	Other/Chemical	21	120	17.5%
	Poor Personal Hygiene	74	441	16.8%
	Food from Unsafe Sources	47	370	12.7%
*	Inadequate Cooking*	2*	7*	*

^{*} 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, chemical contamination, and poor personal hygiene 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 when compared to the other risk factors evaluated during this data collection period.

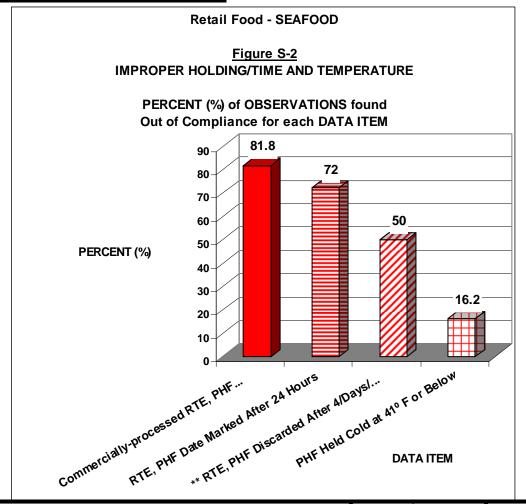
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

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

- Improper Holding/Time and Temperature (42.2%)
- Contaminated Equipment/Protection from Contamination (20.0%)
- Other/Chemical (17.5%)
- Poor Personal Hygiene (16.8%)

Figures S-2 thru S-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 seafood operations to control each of the risk factors during the 2003 data collection.

The other/chemical and food from unsafe sources risk factors all had relatively high IN Compliance percentages. There were a few data items within each of these risk factors that are in need of attention. Information for these data items will be presented as part of the discussion.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	Commercially-processed, RTE, PHF date marked	45	55	81.8%
	RTE, PHF date marked after 24 hours	18	25	72.0%
**	RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F**	9**	18**	50.0%**
	PHF held cold at 41 ⁰F or below	17	105	16.2 %
*	Foods received at temperatures according to Law are cooled to 41 °F within 4 hours.*	0*	8*	*
*	PHF held hot at 140 °F or above*	3*	6*	*
*	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F or below within 4 hours *	2*	5*	*
*	PHF cooled to 70 °F on 2 hours/41 °F in total of 6 hours*	1*	2*	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0*	1*	*
*	Roasts are held at a temperature of 130 °F or above*	0*	0*	*

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

^{**}This data item is included in Figure S-2 even though it has less than twenty total observations. Though there are only a few observations for this data item, it relates directly to the first 2 date marking data items that appear in the Figure.

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:

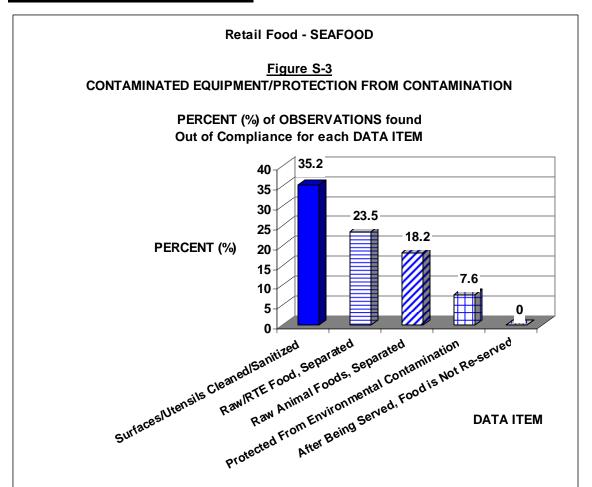
- Date marking of open containers of commercially-processed, ready-to-eat, PHF (81.8%) and ready-to eat, PHF made on site (72.0%)
- Maintaining cold holding temperatures for PHF (16.2%)

Date Marking

Date marking of refrigerated ready-to-eat, PHF, such as seafood salads that may be prepared or sold, is an important food safety system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF 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

Holding PHF 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 need to be assessed and corrective action should be taken if necessary.



DATA ITEM		Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	37	105	35.2%
Raw/RTE foods, separated	23	98	23.5%
Raw animal foods, separated	16	88	18.2%
Protected from environmental contamination	8	105	7.6%
After being served, food is not re-served	0	23	0.0%

Discussion for Figure S-3

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

- Cleaning and sanitizing food contact surfaces and utensils (35.2%)
- Separating raw animal foods from ready-to-eat foods (23.5%)
- Separating raw animal foods from each other (18.2%)

Cleaning and Sanitizing

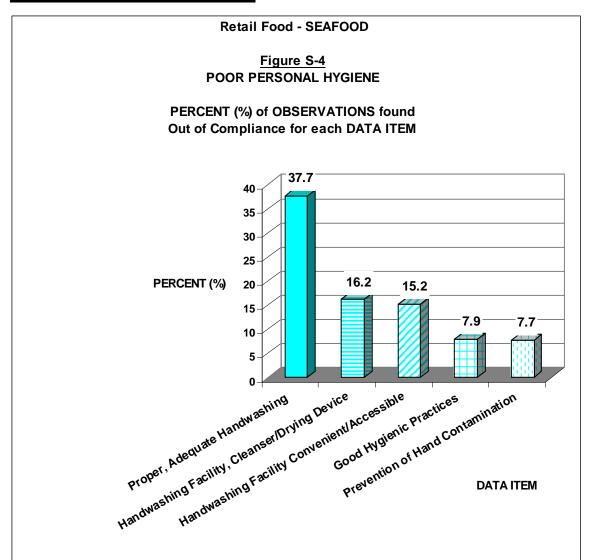
Proper cleaning and sanitization of food contact surfaces is an effective means of preventing cross-contamination. Many different procedures may be involved in the assessment of the management system related to this area. Evaluations should not be restricted to dishwashing procedures but should also include observations on how food preparation tables, cutting boards, and stand-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.

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. Having organized storage systems that include designated areas for 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		Total Obs. (IN & OUT)	% OUT
Proper, adequate handwashing	29	77	37.7%
Handwashing facility, cleanser/drying device	17	105	16.2%
Handwashing facility, convenient/accessible	16	105	15.2%
Good hygienic practices	7	89	7.9%
Prevention of hand contamination	5	65	7.7%

Discussion for Figure S-4

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

- Proper, adequate handwashing (37.7%)
- Handwashing facility, cleanser/drying device (16.2%)
- Handwashing facility, convenient/accessible (15.2%)

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 the lack of proper 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 2003 study show a high IN Compliance percentage (92.3%) for preventing direct hand contamination with food in seafood departments. The retail food management in seafood 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 27

Assessment of the Other/Chemical Category – SEAFOOD

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

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
20	105	19.0%

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 seafood 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.

Discussion for the Food from Unsafe Sources

Table 28

Assessment of the Food from Unsafe Sources Risk Factor - SEAFOOD

Shellstock Tags Retained for 90 Days

# Observations OUT	TOTAL Observations (IN & OUT)	% Observations OUT
31	70	44.3%

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 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 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 should a food-related illness or contamination be associated with shellstock.

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

Table 29

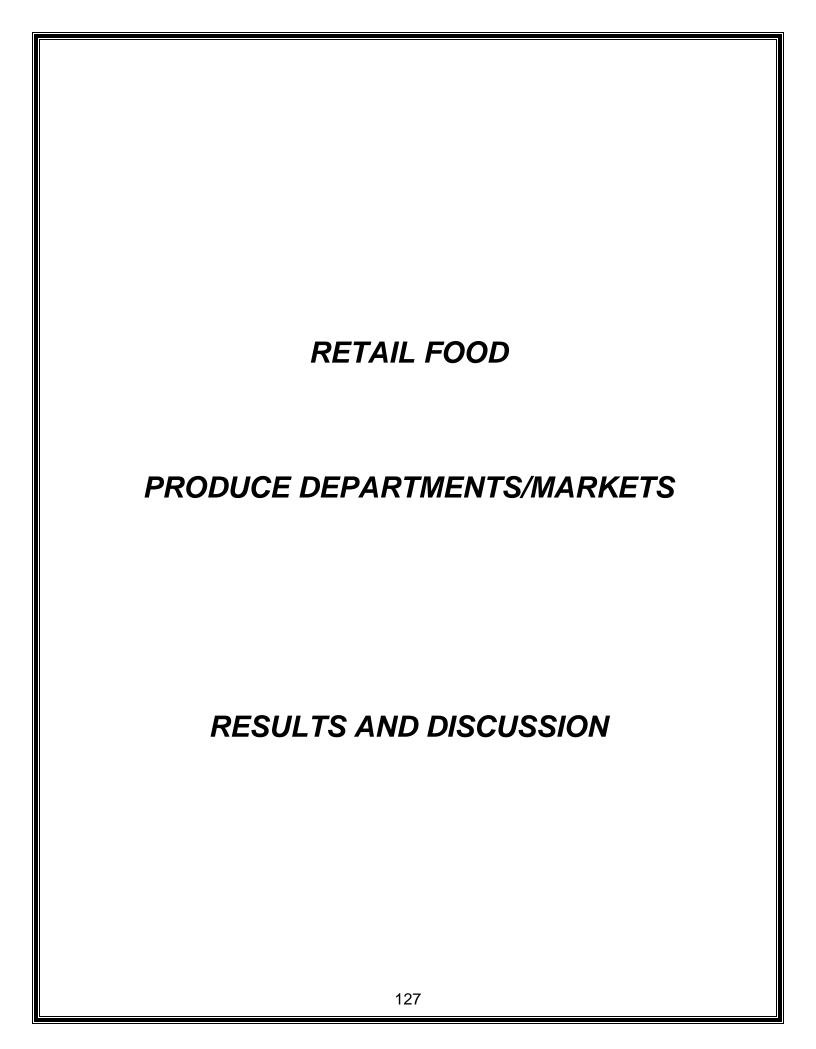
Retail Food Store - SEAFOOD

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

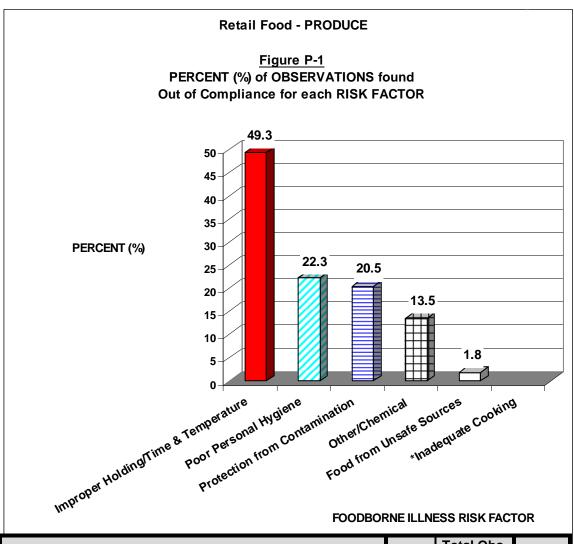
FOODBORNE ILLNESS RISK FACTOR in need of Priority Attention (From Section A)	INDIVIDUAL DATA ITEMS in need of Priority Attention (From Section B)
Improper Holding/ Time & Temperature	Commercially-processed RTE, PHF date marked RTE, PHF date marked after 24 hours RTE, PHF discarded after 4 days/45 °F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

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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	99	201	49.3%
Poor Personal Hygiene	72	323	22.3%
Contaminated Equipment/Protection from Contamination	56	273	20.5%
Other/Chemical	24	178	13.5%
Food from Unsafe Sources	4	223	1.8%

^{*} 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 P-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, 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 when compared to the other risk factors evaluated during this data collection period.

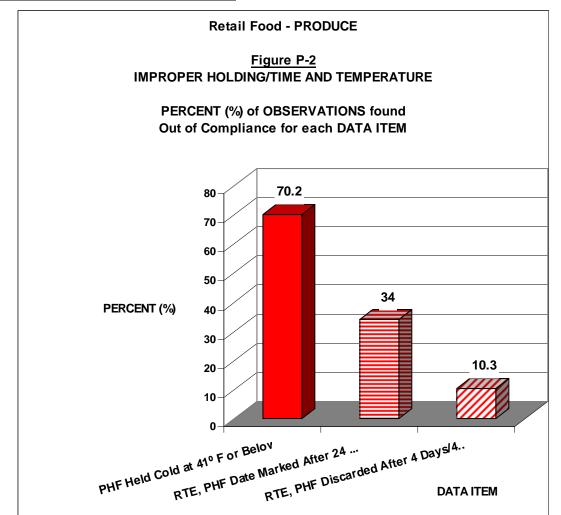
B. Percent of observations found Out of Compliance for each INDIVIDUAL DATA ITEM that comprises a risk factor

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

- Improper Holding/Time Temperature (49.3%)
- Poor Personal Hygiene (22.3%)
- Contaminated Equipment (20.5%)
- Other/Chemical (13.5%)

Figures P-2 thru 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 2003 data collection.

In general, the other/chemical risk factor had a high IN Compliance percentage. There was, however, one data item within this risk factor 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 will be presented.



	DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
	PHF held cold at 41 °F or below	73	104	70.2%
	RTE, PHF date marked after 24 hours	16	47	34.0%
	RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F	3	29	10.3%
*	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F or below within 4 hours*	4*	9*	*
*	Commercially-processed, RTE, PHF date marked*	3*	6*	*
*	PHF held hot at 140 °F or above*	0*	6*	*
*	PHF cooled to 70 °F on 2 hours/41 °F in total of 6 hours*	0*	0*	*
*	When time only is used as a public health control, food is cooked and served within 4 hours*	0*	0*	*
*	Roasts are held at a temperature of 130 °F or above*	0*	0*	*
*	Foods received at temperatures according to Law are cooled to 41 °F within 4 hours.*	0*	0*	*

^{*} These seven remaining 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 systems related to:

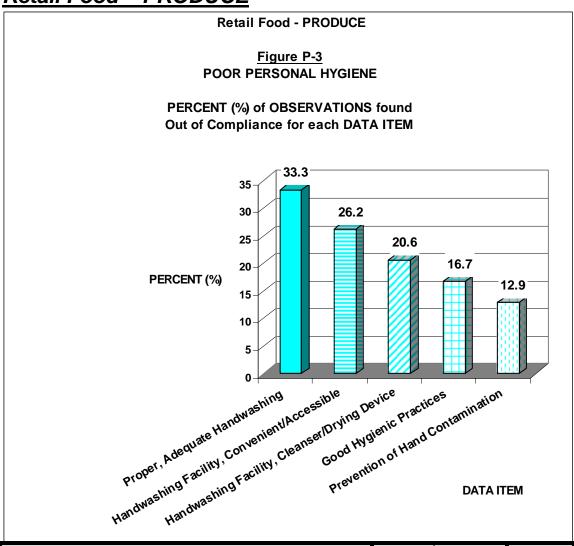
- Maintaining cold holding temperatures for PHF (70.2%)
- Date marking of ready-to eat, PHF made on site (34.0%)

Cold Holding of PHF

Holding PHF 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 need to be assessed and corrective action should be taken if necessary.

Date Marking

Date marking of refrigerated ready-to-eat, PHF is an important food safety system component designed to promote proper food rotation and limit the growth of *Listeria monocytogenes* during cold storage. Discarding ready-to-eat, PHF 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.



DATA ITEM	# OUT	Total Obs. (IN & OUT)	
Proper, adequate handwashing	10	30	33.3%
Handwashing facility, convenient/accessible	28	107	26.2%
Handwashing facility, cleanser/drying device	22	107	20.6%
Good hygienic practices	8	48	16.7%
Prevention of hand contamination	4	31	12.9%

Discussion for Figure P-3

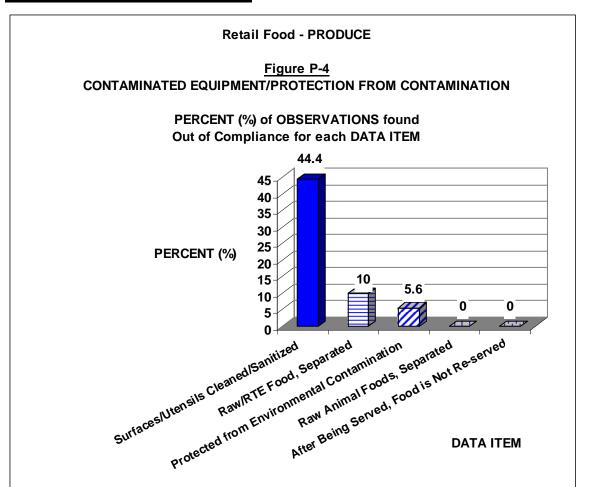
The food safety procedures for the poor personal hygiene risk factor that are most in need of attention include:

- Proper, adequate handwashing (33.3%)
- Handwashing facility, cleanser/drying device (26.2%)
- Handwashing facility, convenient/accessible (20.6%)

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 the lack of proper 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 2003 study show a high IN Compliance percentage (87.1%) for preventing direct hand contamination with food in produce departments. The retail food management in produce departments appear to be making a concerted effort to eliminate bare hand contact with ready-to-eat foods.



DATA ITEM	# OUT	Total Obs. (IN & OUT)	% OUT
Surfaces/Utensils cleaned/sanitized	48	108	44.4%
Raw/RTE foods, separated	2	20	10.0%
Protected from environmental contamination	6	108	5.6%
Raw animal foods, separated	0	9	0.0%
After being served, food is not re-served	0	28	0.0%

<u>Retail Food – PRODUCE</u>

Discussion for Figure P-4

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

Cleaning and sanitizing food contact surfaces and utensils (44.4%)

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 stand in place equipment such as slicers and mixers are cleaned and sanitized between uses.

Discussion for the Other/Chemical Risk Factor

Table 30

Assessment of the Other/Chemical Category - PRODUCE

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

# Observations	TOTAL Observations	% Observations
OUT	(IN & OUT)	OUT
21	108	19.4%

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 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 31

Retail Food Store - PRODUCE

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

DATA ITEMS III Need of Friority 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 held cold at 41 °F or below RTE, PHF date marked after 24 hours RTE, PHF discarded after 4 days/45 °F or 7 days/41 °F	
Poor Personal Hygiene	Proper, adequate handwashing Handwashing facility, convenient/accessible Handwashing Facility, cleanser/drying Device	
Poor Personal Hygiene Contaminated Equipment/ Protection from Contamination	Handwashing facility, convenient/accessible	

IV. RECOMMENDATIONS

The following recommendations are directed toward enhancing the effectiveness of regulatory and industry retail food protection programs. These recommendations are focused 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 encompasses 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.

Section III, Results and Discussion, emphasized 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 to achieve control over foodborne illness risk factors. If the safety of food is to be significantly improved, foodservice and retail food managers must establish effective control 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 systems lies with the management of institutional foodservice, restaurant and retail food store operations. Individual operators responsible for the day-to-day management of these facilities play a key role in preventing foodborne illness.

Food safety management systems can take many forms. Every establishment has some type of a 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, 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*.

The 2000 Baseline Report made the following recommendations for industry to establish active managerial control of foodborne illness risk factors:

- Develop and implement written Standard Operating Procedures (SOPs) that address the risk factors. These SOPs should detail procedures specific to the operation for time/temperature control of potentially hazardous food, personal hygiene, and measures to prevent food from being contaminated.
- **Provide the necessary resources, equipment, and supplies** to implement the SOPs. Items such as temperature measurement devices, preferably thermocouples,

test papers, temperature logs, hand soap, towels, and chemical sanitizers are crucial to the successful control of specific risk factors.

- Assess SOPs to ensure control over all risk factors. Critical limits and measurable standards for control of the risk factors should be incorporated into SOPs. Critical limits provide a means for measuring the effectiveness of an establishment's food safety procedures.
- **Establish monitoring procedures** that focus on critical processes and practices. Monitoring procedures will only be effective if employees are given the knowledge, skills, and responsibility for food safety.
- 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.

The importance of each of these recommendations is reinforced by the results of the 2003 data collection effort. The percentage of establishments that were found to be Out of Compliance with data items related to poor personal hygiene, time/temperature control, and contaminated equipment remained high in 2003. This suggests that industry efforts to achieve active managerial control over these risk factors, and to adequately train employees, still needs to be improved. Managing food safety risk factors must be a fully integrated part of every business operation if it 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 facility type. As a start, industry operators should evaluate how well they are controlling these areas within their own operations. When weaknesses are discovered in the food safety system, action must be initiated to correct the immediate problem and ensure active managerial 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 guidance document, *Managing Food Safety: A HACCP Principles Guide for Operators of Food Establishments at the Retail Level.* The direct FDA web site link to this document is www.cfsan.fda.gov/~dms/hret-toc.html.

B. Recommendations for Regulatory Retail Food Protection Programs

The high percent of establishments 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 the 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. The recommendations below may assist agencies toward this goal.

To assist professionals responsible for regulatory foodservice and retail food inspections, FDA has developed a guidance document, *Managing Food Safety: A Regulator's Guide for Applying HACCP Principles to Risk-Based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems.* As of the printing date of this report, the guidance document was not available on the FDA web site. A copy can be obtained by contacting one of the FDA Regional Retail Food Specialists listed in Appendix J.

Conducting quality inspections

Inspection focus. The risk factors should be the primary focus of every inspection. Inspectors must understand the public health reasons, and be able to correctly apply the underlying regulatory requirements, for the control of each risk factor.

Inspection tools. Use of an inspection form that directs the inspector to routinely document the compliance status (In, Out, Not Observed, Not Applicable) for practices and behaviors related to the risk factors is recommended. An inspector must also be properly equipped with other necessary inspection tools, such as accurate temperature measuring devices (thermocouples) and sanitizer test kits, to assess an establishment's compliance with certain risk factors.

Inspection timing. The time of day that inspections are conducted may need to be varied based on the operation. Inspectors may need flexible schedules to ensure observations of critical food preparation practices that routinely occur before or after the traditional inspector's working hours. Observing and documenting practices related to risk factors, such as cooling of PHF and proper handwashing, may require slightly longer inspections.

Providing on-site education and achieving voluntary compliance

Recognize any existing industry QA and training programs. Inspectors should recognize an establishment's existing quality assurance and employee training programs and reinforce those components that lead to active managerial control of risk factors.

Establish a dialog with operators. Inspectors should discuss out-of-control risk factors with establishment operators and suggest appropriate control measures.

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.

Assist in developing SOPs and Risk Control Plans. Inspectors should assist operators in developing management plans that describe the specific actions to be taken to achieve long-term control of Out of Compliance risk factors. For example, a risk control plan is a concisely written management plan developed by the retail or foodservice operator with input from the regulatory authority. Risk control plans can be used as both education and compliance tools for addressing out-of-control risk factors.

Implementing a consistent and effective enforcement protocol

Develop enforcement procedures. Well-defined, step-by-step procedures are needed for bringing enforcement actions against facilities that repeatedly fail to achieve compliance with requirements related to foodborne illness risk factors.

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

Continuous program improvement

The recommendations described above are captured 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 may use the Standards to evaluate the effectiveness of their food safety program.

While the Program Standards represent the retail food safety program to which we ultimately aspire, they begin by providing a foundation which all regulatory programs can build upon through a continuous improvement process. Managers of regulatory inspection programs are encouraged to review existing practices and procedures to ensure that current program activities target reducing the occurrence of those risk factors identified in Section III, Reports and Discussion. The *Voluntary National Retail Food Regulatory Program Standards* can be accessed and downloaded from FDA's web site: www.cfsan.fda.gov/~dms/ret-toc.html

The Program Standards encourage state and local jurisdictions to establish studies of the occurrence of foodborne illness risk factors that are specific to their geographic area of responsibility. To assist agencies interested in conducting a baseline study in their own jurisdictions, FDA has prepared a manual and developed a software program designed to manage and analyze 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:

- Foods received according to law, cooled to 41 °F (5 °C) within 4 hours
- Cooked PHF 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 (from ambient ingredients) cooled to 41 °F (5 °C) or below within 4 hours
- Roasts, including formed roasts, 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 or they involve processes or operational steps that occur outside traditional regulatory work hours; and documentation of these steps or processes may not have been available at the time of the survey. Other data items related to foods that are not commonly found on the menus of the facility types inspected.

B. Statistical Limitations

Sample Design

Since a random selection of all facility types in the United States would not be possible from a financial or logistical perspective, an alternative method was selected. Comparison sets were developed in five FDA Regions throughout the country. The current picture of compliance with the risk factors reflects the entire U.S. to the extent that the comparison sets 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 being spread across the U.S. in the same pattern that FDA stations its Specialists should give a reasonable approximation of the U.S. compliance picture.

The geographical distribution of Specialists throughout the country 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.

The size of the sample was determined to assure with 95% confidence that if a particular data item has a compliance percentage of no more than 60%, then the study would indicate a compliance rate of no more than 70%.

A challenge inherent in measuring trends is uncontrolled variation in samples. The design of this project controlled this variation by the use of the comparison sets. A typical comparison set 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 such as fast food that were more numerous. In areas with limited numbers of nursing homes and hospitals, a comparison set included a minimum of four establishments.

The establishments in each comparison set were placed in alphabetical order and sequentially numbered. The Specialists then used a table of random numbers, supplied by CFSAN's Division of Mathematics, to select the particular establishment to inspect. Comparison set establishment lists, compiled by the Specialists, have been archived and will be used again in future studies. A different establishment is randomly selected from the same comparison set establishment list for each data collection period. This randomness gives the same chance of selecting establishments having varying degrees of compliance, thus preventing selection bias. Since each comparison set is made up of similar establishments, the sample variability is greatly reduced.

This project is designed to establish a national baseline on the occurrence of foodborne illness risk factors within the foodservice and retail food industry. The way the samples were selected and the size of the data set do not support comparisons of individual Specialists geographical areas, states, cities or even regions of the U.S. Not only would it be statistically inappropriate, but such comparisons might be combined with other information, such as the locations of FDA Retail Food Specialists, to identify some of the likely comparison sets. This information would bias future studies.

In addition, the project is not designed to support comparisons of chains of fast food restaurants or chains of grocery stores. There is no statistical justification for looking at reduced sets of results particular to, e.g., two chains of restaurants and drawing conclusions from the differences.

Comparing data over time

A summary of the 1998 Baseline IN Compliance percentages for ALL data items for each facility was presented in Table 1. This report makes no attempt to analyze the difference in IN Compliance percentages between the 1998 and 2003 results. When designing a study to compare just two periods in time, pairing of facilities is considered important. This study made no attempt to satisfy that condition.

Although the data collected in 2003 is part of a larger study designed to measure changes in IN Compliance percentages over time, this data collection period provided only the second data point in the study progression. Since a minimum of three data collection periods is necessary for the measurement of a trend, the results from the 2003 data collection period presented in this report should be interpreted as a standalone study.

Having three data collection periods is a necessary condition for the determination of a trend, but it is not a sufficient condition. It is theoretically possible to find a trend with three data collection periods, but the impact of the limitations discussed in this section may make documentation of a trend difficult even with the additional data point. Additional data collection periods may need to be included in the study.

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. When analyzing data from two data collection periods, the variation in the number of observations makes it difficult to draw statistical conclusions between the overall compliance percentages or the risk factor compliance percentages. Changes in the number of observations of data items may be attributed to:

- 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 cook risk factor may not be reported, even though the new industry practice represents improved active managerial control.

Quality assurance. After the 1998 data collection period, a thorough quality assurance review of the marking instructions was conducted for each data item. There were a few data items from the original baseline for which it was necessary to clarify the marking instructions and in one case a slight modification to the data item itself was 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 the overall baseline.

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.

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

	1	998		2		
	IN	TOTAL	% IN	IN	TOTAL	% 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, fifty 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 fifty 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 (fifty 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.

VI. NEW AREAS OF STUDY

A. <u>IMPACT OF CERTIFIED MANAGERS ON THE CONTROL OF</u> <u>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 management 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 disease are 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 the important 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 2003 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 Baseline Data Collection Form if the person in charge had been certified by any one of five 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 Baseline 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 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 32.

Table 32
Inspected Facilities With and Without a Certified Food Protection Manager

Facility Type	# Of Inspected Facilities WITH Certified Food Protection Manager	# Of Inspected Facilities WITHOUT Certified Food Protection Manager
Hospitals	80	17
Nursing Homes	54	40
Elementary Schools	56	42
Fast Food Restaurants	71	37
Full Service Restaurants	50	49
Delis	50	58
Meat & Poultry	49	60
Seafood	51	54
Produce	44	64

Impact of Certified Food Protection Managers for each facility type

It appears that the presence of a Certified Food Protection Manager has a positive effect on the overall Percent IN Compliance within some 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 33 on page 149. In the five remaining facility types, the differences were not statistically significant¹.

Table 33

Effect of Manager Certification on the Overall Percent IN Compliance by Facility Type

(2003 Data Collection Form – Sections 1 – 16 (42 Data Items)*

	Man	ager Cer	tified	Mana	ager Not C	ertified	Difference
Facility type	# IN	#OUT	% IN	# IN	# OUT	% IN	(% IN)
Hospitals	1345	347	79.5	277	69	80.1	-0.6
Nursing Homes	864	187	82.2	583	167	77.7	4.5
Elementary Schools	772	158	83.0	562	120	82.4	0.6
Fast Food Restaurants	1014	274	78.7	407	222	64.7	14.0
Full Service Restaurants	678	344	66.3	559	431	56.5	9.8
Delis	660	287	69.7	707	309	69.6	0.1
Meat and Poultry	540	98	84.6	572	181	76.0	8.6
Seafood	643	158	80.3	616	165	78.9	1.4
Produce	439	90	83.0	506	165	75.4	7.6

^{*} The figures in Table 33 do not include the Supplemental Data Items found in Sections 17 – 23 of the Data Collection Form (pages 24 – 25)

Effect of Certified Food Protection Managers on the risk factors

Table 34 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.

Table 34

Risk Factors with Statistically Significant Differences
Between Establishments

WITH and WITHOUT a Certified Food Protection Manager

Facility Type	Risk Factor
Fast Food Restaurants	 Improper Holding/Time and Temperature Contaminated Equipment/Protection from Contamination
Full Service Restaurants	Poor Personal Hygiene;Contaminated Equipment/Protection from Contamination
Meat and Poultry Departments	Poor Personal Hygiene
Produce Departments	 Poor Personal Hygiene

Specific data for each of the six risk factors are presented in Tables 35 A-F. 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.

Food from Unsafe Source

Effect of Manager Certification on Percent IN Compliance by Facility Type

Table 35A

		Manag	er Certif	ied	N	lanager N	lot Certi	fied	
Facility Type	Total IN	Total Out	Total Obs.	% IN	Total IN	Total Out	Total Obs.	% IN	Difference (%IN)
Hospitals	160	0	160	100%	33	1	34	97.1%	2.9%
Nursing Homes	106	4	110	96.4%	78	2	80	97.5%	-1.1%
Elementary Schools	109	3	112	97.3%	81	6	87	93.1%	4.2%
Fast Food Restaurants	139	3	142	97.9%	72	2	74	97.3%	0.6%
Full Service Restaurants	113	18	131	86.3%	108	15	123	87.8%	-1.5%
Delis	97	4	101	96.0%	113	7	120	94.2%	1.8%
Meat and Poultry	108	2	110	98.2%	122	10	132	92.4%	5.8%
Seafood	161	25	186	86.6%	162	22	184	88.0%	-1.4%
Produce	91	0	91	100%	128	4	132	97.0%	3.0%

Inadequate Cooking

Effect of Manager Certification on Percent IN Compliance by Facility Type

Table 35B

		Manager Certified				lanager N	ot Certi	fied	
Facility Type	Total IN	Total Out	Total Obs.	% IN	Total IN	Total Out	Total Obs.	% IN	Difference (%IN)
Hospitals	206	12	218	94.5%	33	4	37	89.2%	5.3%
Nursing Homes	93	4	97	95.9%	60	4	64	93.8%	2.1%
Elementary Schools	60	1	61	98.4%	36	2	38	94.7%	3.7%
Fast Food Restaurants	130	13	143	90.9%	39	4	43	90.7%	0.2%
Full Service Restaurants	104	13	117	88.9%	98	25	123	79.7%	9.2%
Delis	67	4	71	94.4%	72	10	82	87.8%	6.6%
Meat and Poultry	1	0	1	100%	0	1	1	0%	100%
Seafood	3	1	4	75.0%	2	1	3	66.7%	8.3%
Produce	0	0	0	NA	2	0	2	100%	NA

Table 35C

Improper Holding/Time-Temperature

Effect of Manager Certification on Percent IN Compliance by Facility Type

		Manage	r Certifi	ied	N	lanager N	lot Certi	fied	
Facility Type	Total IN	Total Out	Total Obs.	% IN	Total IN	Total Out	Total Obs.	% IN	Difference (%IN)
Hospitals	254	182	436	58.3%	60	30	90	66.7%	-8.4%
Nursing Homes	190	83	273	69.6%	131	59	190	68.9%	0.7%
Elementary Schools	152	65	217	70.1%	113	53	166	68.1%	2.0%
Fast Food Restaurants	187	98	285	65.6%	65	82	147	44.2%	21.4%
Full Service Restaurants	96	146	242	39.7%	74	154	228	32.5%	7.2%
Delis	98	152	250	39.2%	76	163	239	31.8%	7.4%
Meat and Poultry	50	24	74	67.6%	63	24	87	72.4%	-4.8%
Seafood	73	51	124	58.7%	57	44	101	56.4%	2.3%
Produce	54	43	97	55.7%	48	56	104	46.2%	9.5%

Table 35D

Contamination of Equipment/Protection from Contamination

Effect of Manager Certification on Percent IN Compliance by Facility Type

		Manage	r Certifi	ied	N	lanager N	lot Certi	ified	
Facility Type	Total IN	Total Out	Total Obs.	% IN	Total In	Total Out	Total	Percent In	Difference (%IN)
Hospitals	304	70	374	81.3%	66	16	82	80.5%	0.8%
Nursing Homes	201	44	245	82.0%	134	42	176	76.1%	5.9%
Elementary Schools	165	30	195	84.6%	129	16	145	89.0%	-4.4%
Fast Food Restaurants	239	46	285	83.9%	100	49	149	67.1%	16.8%
Full Service Restaurants	148	71	219	67.6%	126	92	218	57.8%	9.8%
Delis	165	49	214	77.1%	168	53	221	76.0%	1.1%
Meat and Poultry	163	40	203	80.3%	168	67	235	71.5%	8.8%
Seafood	161	44	205	78.5%	174	40	214	81.3%	-2.8%
Produce	105	20	125	84.0%	112	36	148	75.7%	8.3%

Table 35E

Poor Personal Hygiene

Effect of Manager Certification on Percent IN Compliance by Facility Type

		Manage	r Certifi	ed	N	lanager N	lot Certi	fied	
Facility Type	Total IN	Total Out	Total Obs.	% IN	Total IN	Total Out	Total Obs.	% IN	Difference (%IN)
Hospitals	331	68	399	83.0%	65	16	81	80.3%	2.7%
Nursing Homes	218	42	260	83.8%	141	49	190	74.2%	9.6%
Elementary Schools	236	42	278	84.9%	164	36	200	82.0%	2.9%
Fast Food Restaurants	257	95	352	73.0%	107	70	177	60.5%	12.5%
Full Service Restaurants	167	80	247	67.6%	117	123	240	48.8%	18.8%
Delis	184	62	246	74.8%	220	62	282	78.0%	-3.2%
Meat and Poultry	163	26	189	86.2%	171	65	236	72.5%	13.7%
Seafood	191	29	220	86.8%	176	45	221	79.6%	7.2%
Produce	118	18	136	86.8%	133	54	187	71.1%	15.7%

Table 35F

Other/Chemical

Effect of Manager Certification on Percent IN Compliance by Facility Type

		Manage	r Certifi	ed	N	lanager N	ot Certi	fied	
Facility Type	Total IN	Total Out	Total Obs.	% IN	Total IN	Total Out	Total Obs.	% IN	Difference (%IN)
Hospitals	90	15	105	85.7%	20	2	22	90.9%	-5.2%
Nursing Homes	56	10	66	84.9%	39	11	50	78.0%	6.9%
Elementary Schools	50	17	67	74.6%	39	7	46	84.8%	-10.2%
Fast Food Restaurants	62	19	81	76.5%	24	15	39	61.5%	15.0%
Full Service Restaurants	50	16	66	75.8%	36	22	58	62.1%	13.7%
Delis	49	16	65	75.4%	58	14	72	80.6%	-5.2%
Meat and Poultry	55	6	61	90.2%	48	14	62	77.4%	12.8%
Seafood	54	8	62	87.1%	45	13	58	77.6%	9.5%
Prodcue	71	9	80	88.8%	83	15	98	84.7%	4.1%

¹ 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.

² The 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 .0005 or less to conclude that a significant difference existed. In this case the probability of committing one or more type 1 errors is .05.

B. SUPPLEMENTAL DATA ITEMS

Although the original forty-two data items used for the 1998 baseline collection were retained in the 2003 data collection, additional data items were added in an effort 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 public health interventions. The following are subject areas that were included in the supplemental data collection:

- 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 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.

Supplemental data items were added to assess whether lowering the cooking temperature of pork had any effect on industry's ability to control this data item. FDA established three separate data items related to the cooking of pork and ratites:

- Cooking of pork, ratites, and injected meats to 155 °F (68 °C) or above for 15 seconds (Data Item 4G);
- Cooking of pork to 145 °F (63 °C) or above for 15 seconds (Data Items 17A);
 and
- Cooking of ratites and injected meats to 155 °F (68 °C) above for 15 seconds (Data Item – 17B).

As shown in Table 36, there were too few observations during the 2003 data collection to make conclusions about what effect, if any, lowering the cooking temperature for pork had on industry's ability to control this data item.

Table 36

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 (Data Item 17A) and Ratites/Injected Meats Cooked to 155 °F (68 °C) (Data Item 17B)

Facility Type	Total IN Observations Cooking All to 155 °F	Total OUT Observations Cooking All to 155 °F	Total	Total IN Observations Cooking Pork to 145 °F; Ratites/Injected Meats to 155 °F	Total OUT Observations Cooking Pork to 145 °F; Ratites/Injected Meats to 155 °F	Total
Hospitals	17	1	18	19	0	19
Nursing Homes	14	0	14	14	0	14
Elementary Schools	0	0	0	0	0	0
Fast Food Restaurants	4	0	4	4	0	4
Full Service Restaurants	11	2	13	14	0	14
Delis	15	1	16	18	0	18
Meat & Poultry	0	0	0	0	0	0
Seafood	0	0	0	0	0	0
Produce	0	0	0	0	0	0

Hot Holding Potentially Hazardous Foods at 135 °F (57 °C)

In the 1997 FDA Food Code and in the 1998 baseline collection, the critical limit for hot holding potentially hazardous food was 140 °F (59 °C). This temperature was lowered to 135 °F (57 °C) in the 2003 Food Code Supplement. 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 this data item.

As shown in Table 37, changing the hot holding to 135 °F (57 °C) had minimal impact on industry's control of this data item. There were not enough observations to draw any conclusions for the meat and poultry, seafood, and produce facility types.

Table 37

Hot Holding at 140 °F (Data Item 8A)

vs.

Hot Holding at 135 °F (Data Item 18A)

Facility Type	Total IN 140 °F	Total Out 140 °F	Total 140 °F	% IN 140 °F	Total IN 135 °F	Total Out 135 °F	Total 135 °F	% IN 135 °F	Difference (%IN)
Hospitals	59	36	95	62.1%	65	30	95	68.4%	6.3%
Nursing Homes	53	17	70	75.7%	54	16	70	77.1%	1.4%
Elementary Schools	61	21	82	74.4%	62	20	82	75.6%	1.2%
Fast Food Rest.	66	28	94	70.2%	71	23	94	75.5%	5.3%
Full Service Rest.	45	42	87	51.7%	48	39	87	55.2%	3.5%
Delis	38	59	97	39.2%	41	56	97	42.3%	3.1%
Meat & Poultry*	0	2	2	0%*	1	1	2	50.0%*	50.0%*
Seafood*	3	3	6	50.0%*	3	3	6	50.0%*	0%*
Produce*	6	0	6	100%*	6	0	6	100%*	0%*

^{*} 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 to the regulatory authority

As shown in Table 38, lack of a formal, written employee health policy was noted in all facility types.

Table 38

WRITTEN EMPLOYEE HEALTH POLICIES (Data Item – 19A)

Facility Type	Total IN	Total Out	Total Obs.	Percent IN
Hospitals	29	68	97	29.9%
Nursing Homes	12	82	94	12.8%
Elementary Schools	12	86	98	12.2%
Fast Food Restaurants	16	92	98	14.8%
Full Service Restaurants	7	92	99	7.1%
Delis	18	90	108	16.7%
Meat & Poultry	18	91	109	16.5%
Seafood	17	88	105	16.2%
Produce	18	90	108	16.7%

Juice 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 thirteen total observations of juice treatment were noted during the 2003 baseline 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 (7.2 °C) and the cooling of raw shell eggs by being placed under refrigeration at an ambient temperature of 45 °F (7.2 °C) after receipt.

As shown in Table 39, 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. 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 conclusion for any of the facility types.

Table 39

Cold Holding of Eggs (Data Item – 22A)

	Total	Total	Total	
Facility Type	IN	Out	Obs.	Percent IN
Hospitals	75	0	75	100.0%
Nursing Homes	77	2	79	97.5%
Elementary Schools	30	0	30	100.0%
Fast Food Restaurants	29	2	31	93.6%
Full Service Restaurants	71	13	84	84.5%
Delis	18	3	21	85.7%
Meat & Poultry	4	1	5	80.0%
Seafood	0	0	0	
Produce	11	4	15	73.3%

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 40, there were no Out of Compliance observations in institutional facility types for data item 23A. This indicates managerial control of this item in institutional foodservice settings.

Table 40

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

Facility Type	Total IN	Total Out	Total Obs.	Percent IN 23A
Hospitals	96	0	96	100%
Nursing Homes	90	0	90	100%
Elementary Schools	85	0	85	100%

Elementary schools and hospitals appear to have active managerial control over data items 23B (Table 41) and 23C (Table 42) related to the use of pasteurized eggs and no raw or undercooked animal foods being served, respectively. The data suggests that some nursing homes may need to ensure compliance with requirements pertaining to the use of unpasteurized eggs in light of the risk associated with *Salmonella* Enteritidis in undercooked shell eggs.

Table 41

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

Facility Type	Total IN	Total OUT	Total Obs.	Percent IN 23B
Hospitals	71	4	75	94.7%
Nursing Homes	47	18	65	72.3%
Elementary Schools	37	4	41	90.2%

Table 42

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 23C
Hospitals	90	2	92	97.8%
Nursing Homes	73	10	83	87.9%
Elementary Schools	70	0	70	100%

APPENDICES

DATA SUMMARY (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							
1A	prepared/canned foods	97	0	0	0			
	All shellfish from NSSP listed sources. No recreationally caught							
1B	shellfish received or sold	0	0	0	97			
40	Game, wild mushrooms harvested with approval of Regulatory	0	_	1	06			
1C	Authority Food received at proper temperatures/protected from contamination	0	0	ı	96			
	during transportation and receiving/food is safe, unadulterated							
2A	daning transportation and receiving recalls care, and date and	96	1	0	0			
	Shellstock tags/labels retained for 90 days from the data the							
3A	container is emptied	0	0	0	97			
20	As required, written documentation of parasite destruction maintained	0	_	_	07			
3B	for 90 days for fish products CCP monitoring records maintained in accordance with HACCP plan	0	0	0	97			
3C	when required	0	0	0	97			
	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	40	0		00			
4A	immediate service cooked to155 °F (68 °C) for 15 seconds	10	0	57	30			
4B	Comminuted Fish, Meats, Game animals cooked to 155 °F (68 °C) for 15 seconds	40	1	54	2			
46	Roasts, including formed roasts, are cooked to 130 °F	40	!	34				
	(54 °C) for 112 minutes or as Chart specified and according to oven							
4C	parameters per Chart	8	1	76	12			
	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,							
	stuffed ratites, or stuffing containing fish, meat, poultry or ratites							
4D	cooked to 165 °F (74 °C) for 15 seconds	40	7	48	2			
4E	Wild game animals cooked to 165 °F (74 °C) for 15 seconds	0	0	1	96			
	Raw animal foods cooked in microwave are rotated, stirred, covered, and heated to 165 °F (74 °C). Food is allowed to stand							
4F	covered for 2 minutes after cooking	0	0	6	91			
	Pork, ratites, injected meats are cooked to 155 °F (68 °C) for 15							
4G	seconds.	17	1	69	10			
4H	All other PHF cooked to 145 °F (63 °C) for 15 seconds	41	0	54	2			
	PHF that is cooked and cooled on premises is rapidly reheated to							
5A	165 °F (74 °C) for 15 seconds for hot holding	30	2	62	3			
5B	Food reheated in a microwave is heated to 165 °F (74 °C) or higher	5	1	25	66			
5C	Commercially processed ready-to-eat food, reheated to 140 °F	46	3	45	3			
30	(60 °C) or above for hot holding Remaining unsliced portions of roasts are reheated for hot	40	3	40	3			
5D	holding using minimum oven parameters	2	0	68	27			

DATA SUMMARY (page 2 of 4)

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
#	Improper Holding/Time & Temperature	114	001	NO	IVA
	Cooked PHF 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	16	23	57	1
6B	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F (5 °C) or below within 4 hours	20	9	59	9
6C	Foods received at a temperature according to Law are cooled to 41 °F (5 °C) within 4 hours	12	2	82	1
7A	PHF is maintained at 41 °F (5 °C) or below, except during preparation, cooking, cooling or when time is used as a public health control.	41	56	0	0
8A	PHF 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.	59	36	2	0
8B	Roasts are held at a temperature of 130 °F (54 °C) or above	5	0	71	21
9A	Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)	60	33	2	2
9B	Discard RTE PHF and/or opened commercial container exceeding 7 days at \leq 41 °F (5 °C) or 4 days at \leq 45 °F (7 °C)	55	12	29	1
9C	Opened Commercial container of prepared ready-to-eat PHF is date marked as required	44	41	10	2
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	2	0	4	91
	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	75	22	0	0
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	82	14	1	0
10C	Food is protected from environmental contamination – critical Items	85	12	0	0
10D	After being served or sold to a consumer, food is not re-served	68	1	20	8
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	60	37	0	0

DATA SUMMARY (page 3 of 4)

DATA	DATA GOMMANT (page 6 of 4)							
ITEM	DATA ITEM	#	#	#	#			
#		IN	OUT	NO	NA			
	Poor Personal Hygiene							
12A	Hands are clean and properly washed when and as required	63	32	2	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-	79	17	1	0			
13A	service or single-use articles							
14A	Employees do not contact exposed, ready-to-eat food with their bare hands.	86	9	2	0			
14A	Handwash facilities conveniently located and accessible for	00	9		U			
15A	Employees	82	15	0	0			
	Handwash facilities supplied with hand cleanser/sanitary							
15B	towels/hand drying devices	86	11	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	29	0	0	68			
IOA	Poisonous or toxic materials, chemicals, lubricants, pesticides,	29	- 0	U	00			
	medicines, first aid supplies, and other personal care items are							
16B	properly identified, stored and used	80	17	0	0			
400	Poisonous or toxic materials held for retail sale are properly stored	4			00			
16C	Complemental Home Nav. Areas of Cturbs	1	0	0	96			
474	Supplemental Items – New Areas of Study	40	0	00	40			
17A	Pork is cooked to 145 °F (63 °C) or above for 15 seconds	18	0	69	10			
17B	Ratites and injected meats are cooked to 155 °F (68 °C) for 15 seconds	1	0	76	20			
	PHF is maintained at 135 °F (57 °C) or above, except during	-						
	preparation, cooking, or cooling or when time is used as a public							
18A	health control	65	30	1	1			
	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 Food Code.	29	68	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	3	0	0	94			
ZUA	After receiving, raw shell eggs are immediately placed under			-	54			
	refrigeration that maintains ambient air temperature of 45 °F (7 °C) or							
21A	less	18	0	60	19			

DATA SUMMARY (page 4 of 4)

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
22A	After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45 °F (7 °C) or less	75	0	3	19
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	96	0	0	1
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 Baseline 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	71	4	19	3
23C	Raw or partially cooked animal food and raw seed sprouts not served	90	2	2	3

APPENDIX B – NURSING HOMES

DATA SUMMARY (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							
1A	prepared/canned foods	94	0	0	0			
1B	All shellfish from NSSP listed sources. No recreationally caught shellfish received or sold	1	0	0	93			
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	0	0	1	93			
	Food received at proper temperatures/protected from contamination during transportation and receiving/food is safe, unadulterated							
2A		88	6	0	0			
3A	Shellstock tags/labels retained for 90 days from the data the container is emptied	0	0	3	91			
3B	As required, written documentation of parasite destruction maintained for 90 days for fish products	0	0	2	92			
3C	CCP monitoring records maintained in accordance with HACCP plan when required	1	0	0	93			
	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 immediate service cooked to155 °F (68 °C) for 15 seconds	6	3	65	20			
	Comminuted Fish, Meats, Game animals cooked to 155 °F (68 °C)							
4B	for 15 seconds	26	0	65	3			
40	Roasts, including formed roasts, are cooked to 130 °F (54 °C) for 112 minutes or as Chart specified and according to oven parameters per	4		70	4.4			
4C	Chart Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,	4	0	79	11			
45	stuffed ratites, or stuffing containing fish, meat, poultry or ratites	00	,	07	4			
4D 4E	cooked to 165 °F (74 °C) for 15 seconds Wild game animals cooked to 165 °F (74 °C) for 15 seconds	22	0	67 2	92			
	Raw animal foods cooked in microwave are rotated, stirred,				02			
	covered, and heated to 165 °F (74 °C). Food is allowed to stand	_			0.4			
4F	covered for 2 minutes after cooking Pork, ratites, injected meats are cooked to 155 °F (68 °C) for 15	0	0	3	91			
4G	seconds.	14	0	71	9			
4H	All other PHF cooked to 145 °F (63 °C) for 15 seconds	32	0	56	6			
5.4	PHF that is cooked and cooled on premises is rapidly reheated to	12	3	62	16			
5A 5B	165 °F (74 °C) for 15 seconds for hot holding Food reheated in a microwave is heated to 165 °F (74 °C) or higher	1	0	63 24	16 69			
- JD	Commercially processed ready-to-eat food, reheated to 140 °F	<u> </u>			- 55			
5C	(60 °C) or above for hot holding	33	1	48	12			
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	3	0	64	27			

APPENDIX B - NURSING HOMES

DATA SUMMARY (page 2 of 4)

DATA	DATA COMMANT (page 2 of 4)				
DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Improper Holding/Time & Temperature				
	Cooked PHF is cooled from 140 °F (60 °C) to 70 °F (21 °C)				
6A	within 2 hours and from 140 $^{\circ}$ F (60 $^{\circ}$ C) to 41 $^{\circ}$ F (5 $^{\circ}$ C) or below within 6 hours	9	17	57	11
6B	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F (5 °C) or below within 4 hours	7	7	72	8
6C	Foods received at a temperature according to Law are cooled to 41 °F (5 °C) within 4 hours	25	3	65	1
7A	PHF is maintained at 41 °F (5 °C) or below, except during preparation, cooking, cooling or when time is used as a public health control.	60	34	0	0
8A	PHF 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.	53	17	18	6
8B	Roasts are held at a temperature of 130 °F (54 °C) or above	5	1	67	21
9A	Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)	61	26	2	5
9B	Discard RTE PHF and/or opened commercial container exceeding 7 days at \leq 41 °F (5 °C) or 4 days at \leq 45 °F (7 °C)	56	5	30	3
9C	Opened Commercial container of prepared ready-to-eat PHF is date marked as required	43	32	11	8
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	2	0	2	90
	Contaminated Equipment/Protection from Contam	inati	ion		
	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods				
10A	from cooked ready-to-eat food Raw animal foods are separated from each other during storage,	65	23	2	4
10B	preparation, holding, and display Food is protected from environmental contamination – critical	74	14	3	3
10C	Items	81	13	0	0
10D	After being served or sold to a consumer, food is not re-served	56	1	24	13
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	59	35	0	0

APPENDIX B - NURSING HOMES

DATA SUMMARY (page 3 of 4)

DATA	DATA COMMINANT (page C CT +)						
ITEM	DATA ITEM	#	#	#	#		
#		IN	OUT	NO	NA		
	Poor Personal Hygiene						
12A	Hands are clean and properly washed when and as required	51	34	9	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						
424	food, clean equipment, utensils, linens, unwrapped single-	77	11	6	0		
13A	service or single-use articles Employees do not contact exposed, ready-to-eat food with their bare						
14A	hands.	71	18	5	0		
	Handwash facilities conveniently located and accessible for						
15A	employees	78	16	0	0		
15B	Handwash facilities supplied with hand cleanser/sanitary	82	12	0	0		
196	towels/hand drying devices	02	12	U	U		
	Other/Chemical		I				
	If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw						
16A	consumption	22	0	0	72		
	Poisonous or toxic materials, chemicals, lubricants, pesticides,						
	medicines, first aid supplies, and other personal care items are			_			
16B	properly identified, stored and used	73	21	0	0		
16C	Poisonous or toxic materials held for retail sale are properly stored	0	0	0	94		
	Supplemental Items – New Areas of Study		•				
17A	Pork is cooked to 145 °F (63 °C) or above for 15 seconds	14	0	71	9		
	Ratites and injected meats are cooked to 155 °F (68 °C) for 15						
17B	Seconds	0	0	73	21		
	PHF is maintained at 135 °F (57 °C) or above, except during						
18A	preparation, cooking, or cooling or when time is used as a public health control	54	16	18	6		
10/	Facility has a written policy that is consistent with 2-201 of the <i>Food</i>	<u> </u>	- '0	-10			
	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						
19A	employee responsibility to notify management of symptoms and illnesses identified in the <i>Food Code</i> .	12	82	0	0		
137	When packaged in a food establishment, juice is treated under a	12	02				
	HACCP Plan to reduce pathogens or be labeled as specified in the						
20A	Food Code	3	0	0	91		
	After receiving, raw shell eggs are immediately placed under						
21A	refrigeration that maintains ambient air temperature of 45 °F (7 °C) or less	32	0	54	8		
ZIA	1000	JZ	U	J 4	O		

APPENDIX B - NURSING HOMES

DATA SUMMARY (page 4 of 4)

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.)				
22A	After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45 °F (7 °C) or less	77	2	5	10
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	90	0	1	3
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 Baseline 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.	47	18	20	9
23C	Raw or partially cooked animal food and raw seed sprouts not served	73	10	6	5

DATA SUMMARY (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						
1A	prepared/canned foods	98	0	0	0		
1B	All shellfish from NSSP listed sources. No recreationally caught shellfish received or sold	0	3	0	95		
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	0	0	2	96		
2A	Food received at proper temperatures/protected from contamination during transportation and receiving/food is safe, unadulterated	92	6	0	0		
3A	Shellstock tags/labels retained for 90 days from the data the container is emptied	0	0	2	96		
3B	As required, written documentation of parasite destruction maintained for 90 days for fish products	0	0	2	96		
3C	CCP monitoring records maintained in accordance with HACCP plan when required	0	0	0	98		
	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	1	0	18	79		
4B	Comminuted Fish, Meats, Game animals cooked to 155 °F (68 °C) for 15 seconds	9	0	27	62		
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	20	78		
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	2	0	37	59		
4E	Wild game animals cooked to 165 °F (74 °C) for 15 seconds	0	0	0	98		
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	98		
4G	Pork, ratites, injected meats are cooked to 155 °F (68 °C) for 15 seconds.	0	0	14	84		
4H	All other PHF cooked to 145 °F (63 °C) for 15 seconds	17	0	21	60		
5A	PHF that is cooked and cooled on premises is rapidly reheated to 165 °F (74 °C) for 15 seconds for hot holding	9	1	43	45		
5B	Food reheated in a microwave is heated to 165 °F (74 °C) or higher	0	1	12	85		
5C	Commercially processed ready-to-eat food, reheated to 140 °F (60 °C) or above for hot holding	58	1	27	12		
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	0	0	11	87		

DATA SUMMARY (page 2 of 4)

DATA	DATA COMMANT (page 2 of 4)							
DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA			
Improper Holding/Time & Temperature								
	Cooked PHF is cooled from 140 °F (60 °C) to 70 °F (21 °C)							
6A	within 2 hours and from 140 $^{\circ}$ F (60 $^{\circ}$ C) to 41 $^{\circ}$ F (5 $^{\circ}$ C) or below within 6 hours	3	5	57	33			
6B	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F (5 °C) or below within 4 hours	6	1	59	32			
6C	Foods received at a temperature according to Law are cooled to 41 °F (5 °C) within 4 hours	25	1	67	5			
7A	PHF is maintained at 41 °F (5 °C) or below, except during preparation, cooking, cooling or when time is used as a public health control.	70	28	0	0			
8A	PHF 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.	61	21	13	3			
8B	Roasts are held at a temperature of 130 °F (54 °C) or above	0	0	18	80			
9A	Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)	29	22	11	36			
9B	Discard RTE PHF and/or opened commercial container exceeding 7 days at \leq 41 °F (5 °C) or 4 days at \leq 45 °F (7 °C)	35	8	33	22			
9C	Opened Commercial container of prepared ready-to-eat PHF is date marked as required	32	32	8	26			
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	4	0	0	94			
	Contaminated Equipment/Protection from Contam	inati	ion					
	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods							
10A	from cooked ready-to-eat food	41	7	4	46			
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	34	1	2	61			
10C	Food is protected from environmental contamination – critical ltems	87	11	0	0			
10D	After being served or sold to a consumer, food is not re-served	59	2	22	15			
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	73	25	0	0			

DATA SUMMARY (page 3 of 4)

DATA	DATA COMMANT (page COT4)						
ITEM	DATA ITEM	#	#	#	#		
#		IN	OUT	NO	NA		
Poor Personal Hygiene							
12A	Hands are clean and properly washed when and as required	64	30	4	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-	83	13	2	0		
13A	service or single-use articles						
14A	Employees do not contact exposed, ready-to-eat food with their bare hands.	77	15	6	0		
144	Handwash facilities conveniently located and accessible for	11	13	0	0		
15A	employees	85	13	0	0		
	Handwash facilities supplied with hand cleanser/sanitary						
15B	towels/hand drying devices	91	7	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	13	0	0	85		
IOA	Poisonous or toxic materials, chemicals, lubricants, pesticides,	13	- 0	U	00		
	medicines, first aid supplies, and other personal care items are						
16B	properly identified, stored and used	74	24	0	0		
	Poisonous or toxic materials held for retail sale are properly stored						
16C		2	0	0	96		
4-4	Supplemental Items – New Areas of Study				0.4		
17A	Pork is cooked to 145 °F (63 °C) or above for 15 seconds	0	0	14	84		
17B	Ratites and injected meats are cooked to 155 °F (68 °C) for 15 seconds	0	0	14	84		
	PHF is maintained at 135 °F (57 °C) or above, except during				<u> </u>		
	preparation, cooking, or cooling or when time is used as a public						
18A	health control	62	20	12	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 Food Code.	12	86	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	2	0		96		
20A	Food Code After receiving, raw shell eggs are immediately placed under		0	0	90		
	refrigeration that maintains ambient air temperature of 45 °F (7 °C) or						
21A	less	16	0	15	67		

DATA SUMMARY (page 4 of 4)

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
22A	After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45 °F (7 °C) or less	30	0	2	66
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	85	0	4	9
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 Baseline 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.	37	4	8	49
23C	Raw or partially cooked animal food and raw seed sprouts not served	70	0	0	28

APPENDIX D – FAST FOOD RESTAURANTS

DATA SUMMARY (page 1 of 4)

DATA	DATA SOMMANT (page 1 of 4)						
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	108	0	0	0		
1B	All shellfish from NSSP listed sources. No recreationally caught shellfish received or sold	0	0	0	108		
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	0	0	2	106		
	Food received at proper temperatures/protected from contamination during transportation and receiving/food is safe, unadulterated				100		
2A	Shellstock tags/labels retained for 90 days from the data the	103	5	0	0		
3A	container is emptied As required, written documentation of parasite destruction	0	0	1	107		
3B	maintained for 90 days for fish products	0	0	0	108		
3C	CCP monitoring records maintained in accordance with HACCP plan when required	0	0	0	108		
	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	8	0	20	80		
4B	immediate service cooked to155 °F (68 °C) for 15 seconds Comminuted Fish, Meats, Game animals cooked to 155 °F	42	8	18	40		
4B 4C	(68 °C) for 15 seconds 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	4	0	6	98		
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	48	1	28	31		
4E	Wild game animals cooked to 165 °F (74 °C) for 15 seconds	0	0	0	108		
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	4	104		
4G	Pork, ratites, injected meats are cooked to 155 °F (68 °C) for 15 seconds.	4	0	35	69		
4H	All other PHF cooked to 145 °F (63 °C) for 15 seconds PHF that is cooked and cooled on premises is rapidly reheated to	23	0	37	48		
5A	165 °F (74 °C) for 15 seconds for hot holding	6	4	37	61		
5B	Food reheated in a microwave is heated to 165 °F (74 °C) or higher	3	0	23	82		
5C	Commercially processed ready-to-eat food, reheated to 140 °F (60 °C) or above for hot holding	31	4	37	36		
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	0	0	7	101		

APPENDIX D – FAST FOOD RESTAURANTS

DATA SUMMARY (page 2 of 4)

DATA	DATA COMMANT (page 2 of 4)							
DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA			
Improper Holding/Time & Temperature								
	Cooked PHF is cooled from 140 °F (60 °C) to 70 °F (21 °C)							
6A	within 2 hours and from 140 $^{\circ}$ F (60 $^{\circ}$ C) to 41 $^{\circ}$ F (5 $^{\circ}$ C) or below within 6 hours	2	10	55	41			
6B	PHF (prepared from ingredients at ambient temperature) is cooled to 41 $^{\circ}$ F (5 $^{\circ}$ C) or below within 4 hours	7	5	36	60			
6C	Foods received at a temperature according to Law are cooled to 41 °F (5 °C) within 4 hours	12	2	76	18			
7A	PHF is maintained at 41 °F (5 °C) or below, except during preparation, cooking, cooling or when time is used as a public health control.	47	61	0	0			
8A	PHF 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.	66	28	3	11			
8B	Roasts are held at a temperature of 130 °F (54 °C) or above	3	3	3	99			
9A	Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)	35	24	4	45			
9B	Discard RTE PHF and/or opened commercial container exceeding 7 days at \leq 41 °F (5 °C) or 4 days at \leq 45 °F (7 °C)	38	5	46	19			
9C	Opened Commercial container of prepared ready-to-eat PHF is date marked as required	28	38	8	34			
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	14	4	1	89			
	Contaminated Equipment/Protection from Contam	inati	ion					
	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods	7.1	4-		4.7			
10A	from cooked ready-to-eat food Raw animal foods are separated from each other during storage,	74	17	0	17 27			
10B 10C	preparation, holding, and display Food is protected from environmental contamination – critical Items	75 91	6 17	0	0			
10C	After being served or sold to a consumer, food is not re-served	46	0	37	25			
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	53	55	0	0			

APPENDIX D – FAST FOOD RESTAURANTS

DATA SUMMARY (page 3 of 4)

DATA	DATA GOMMANT (page 6 of 4)						
ITEM	DATA ITEM	#	#	#	#		
#		IN	OUT	NO	NA		
Poor Personal Hygiene							
12A	Hands are clean and properly washed when and as required	48	56	4	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-	81	23	4	0		
13A	service or single-use articles						
	Employees do not contact exposed, ready-to-eat food with their bare						
14A	hands.	52	53	3	0		
15A	Handwash facilities conveniently located and accessible for Employees	92	16	0	0		
134	Handwash facilities supplied with hand cleanser/sanitary	92	10	U	U		
15B	towels/hand drying devices	91	17	0	0		
	Other/Chemical						
	If used, only approved food or color additives. Sulfites are not						
	applied to fresh fruits and vegetables intended for raw		_	_			
16A	consumption	12	0	0	96		
	Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are						
16B	properly identified, stored and used	74	34	0	0		
	Poisonous or toxic materials held for retail sale are properly stored		<u> </u>				
16C	, ,	0	0	0	108		
	Supplemental Items – New Areas of Study						
17A	Pork is cooked to 145 °F (63 °C) or above for 15 seconds	3	0	35	70		
470	Ratites and injected meats are cooked to 155 °F (68 °C) for 15		_	00	74		
17B	seconds	1	0	36	71		
	PHF is maintained at 135 °F (57 °C) or above, except during preparation, cooking, or cooling or when time is used as a public						
18A	health control	71	23	2	12		
	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						
19A	employee responsibility to notify management of symptoms and illnesses identified in the <i>Food Code</i> .	16	92	0	0		
	When packaged in a food establishment, juice is treated under a		<u> </u>	Ť			
	HACCP Plan to reduce pathogens or be labeled as specified in the						
20A	Food Code	0	1	0	107		
	After receiving, raw shell eggs are immediately placed under						
21A	refrigeration that maintains ambient air temperature of 45 °F (7 °C) or	5	0	25	77		
ZIA	less	၁	U	25	11		

APPENDIX D – FAST FOOD RESTAURANTS

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
22A	After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45 °F (7 °C) or less	29	2	0	77
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	108
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 Baseline 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	108
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	108

DATA ITEM	DATA ITEM	#	#	#	#				
#		IN	OUT	NO	NA				
Food From Unsafe Sources									
	All food from Regulated Food Processing Plants/No Home			_	_				
1A	prepared/canned foods	98	1	0	0				
1B	All shellfish from NSSP listed sources. No recreationally caught shellfish received or sold	24	4	0	71				
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	2	0	2	95				
	Food received at proper temperatures/protected from contamination								
2A	during transportation and receiving/food is safe, unadulterated	91	8	0	0				
3A	Shellstock tags/labels retained for 90 days from the data the container is emptied	6	13	4	76				
	As required, written documentation of parasite destruction maintained								
3B	for 90 days for fish products	0	6	1	92				
3C	CCP monitoring records maintained in accordance with HACCP plan when required	0	1	0	98				
	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	0.4	0	- 4	0.4				
4A	immediate service cooked to155 °F (68 °C) for 15 seconds	21	3	54	21				
4B	Comminuted Fish, Meats, Game animals cooked to 155 °F (68 °C) for 15 seconds	41	3	43	12				
75	Roasts, including formed roasts, are cooked to 130 °F (54 °C) for 112	71		70	12				
	minutes or as Chart specified and according to oven parameters per								
4C	Chart	2	0	43	54				
	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,								
4D	stuffed ratites, or stuffing containing fish, meat, poultry or ratites	38	0	49	3				
4D 4E	cooked to 165 °F (74 °C) for 15 seconds Wild game animals cooked to 165 °F (74 °C) for 15 seconds	0	9	3	95				
76	Raw animal foods cooked in microwave are rotated, stirred,		- '-		55				
	covered, and heated to 165 °F (74 °C). Food is allowed to stand								
4F	covered for 2 minutes after cooking	0	0	1	98				
4.0	Pork, ratites, injected meats are cooked to 155 °F (68 °) for 15				00				
4G 4H	seconds.	11 41	2 5	60	26				
411	All other PHF cooked to 145 °F (63 °C) for 15 seconds PHF that is cooked and cooled on premises is rapidly reheated to	41	5	49	4				
5A	165 °F (74 °C) for 15 seconds for hot holding	25	11	54	9				
5B	Food reheated in a microwave is heated to 165 °F (74 °C) or higher	3	1	21	74				
	Commercially processed ready-to-eat food, reheated to 140 °F								
5C	(60 °C) or above for hot holding	19	2	45	33				
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	1	1	31	66				

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA						
#	Improper Holding/Time & Temperature										
	Cooked PHF is cooled from 140 °F (60 °C) to 70 °F (21 °C)										
6A	within 2 hours and from 140 $^{\circ}$ F (60 $^{\circ}$ C) to 41 $^{\circ}$ F (5 $^{\circ}$ C) or below within 6 hours	10	34	51	4						
6B	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F (5 °C) or below within 4 hours	9	7	61	22						
6C	Foods received at a temperature according to Law are cooled to 41 °F (5 °C) within 4 hours	12	6	80	1						
7A	PHF is maintained at 41 °F (5 °C) or below, except during preparation, cooking, cooling or when time is used as a public health control.	22	77	0	0						
8A	PHF 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.	45	42	11	1						
8B	Roasts are held at a temperature of 130 °F (54 °C) or above	2	3	32	62						
9A	Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)	24	69	2	4						
9B	Discard RTE PHF and/or opened commercial container exceeding 7 days at \leq 41 °F (5 °C) or 4 days at \leq 45 °F (7 °C)	20	16	59	4						
9C	Opened Commercial container of prepared ready-to-eat PHF is date marked as required	24	43	10	22						
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	2	3	3	91						
	Contaminated Equipment/Protection from Contam	inat	ion								
404	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods	5 4	45	4							
10A 10B	from cooked ready-to-eat food Raw animal foods are separated from each other during storage, preparation, holding, and display	51 70	45 24	1	2 4						
10D	Food is protected from environmental contamination – critical Items	64	35	0	0						
10D	After being served or sold to a consumer, food is not re-served	46	3	39	11						
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	43	56	0	0						

DATA	DATA COMMINANT (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	27	72	0	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, unwrapped single-	64	33	0	0					
13A	service or single-use articles	•								
	Employees do not contact exposed, ready-to-eat food with their bare									
14A	hands.	40	53	6	0					
154	Handwash facilities conveniently located and accessible for	76	22	0						
15A	employees Handwash facilities supplied with hand cleanser/sanitary	76	23	U	0					
15B	towels/hand drying devices	77	22	0	0					
	Other/Chemical									
	If used, only approved food or color additives. Sulfites are not									
	applied to fresh fruits and vegetables intended for raw									
16A	consumption	25	0	0	74					
	Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are									
16B	properly identified, stored and used	61	38	0	0					
	Poisonous or toxic materials held for retail sale are properly stored									
16C		0	0	0	99					
	Supplemental Items – New Areas of Study									
17A	Pork is cooked to 145 °F (63 °C) or above for 15 seconds	10	0	63	26					
17B	Ratites and injected meats are cooked to 155 °F (68 °C) for 15	4	0	62	33					
176	seconds PHF is maintained at 135 °F (57 °C) or above, except during	4	U	02	33					
	preparation, cooking, or cooling or when time is used as a public									
18A	health control	48	39	10	2					
	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> .	7	92	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	1	0	0	98					
	After receiving, raw shell eggs are immediately placed under refrigeration that maintains ambient air temperature of 45 °F (7 °C) or									
21A	less	10	2	76	11					
-17		.0	<u>-</u>	. 0						

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
22A	After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45 °F (7 °C) or less	71	13	4	11
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 Baseline 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	99
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	99

APPENDIX F – DELI DEPARTMENTS/STORES

DATA	DATA SOMMAKT (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	407							
1A	prepared/canned foods All shellfish from NSSP listed sources. No recreationally caught	107	1	0	0				
1B	shellfish received or sold	0	0	0	108				
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	0	0	0	108				
10	Food received at proper temperatures/protected from contamination		0	-	100				
2A	during transportation and receiving/food is safe, unadulterated	103	5	0	0				
3A	Shellstock tags/labels retained for 90 days from the data the container is emptied	0	0	0	108				
3B	As required, written documentation of parasite destruction maintained for 90 days for fish products	0	2	0	106				
3C	CCP monitoring records maintained in accordance with HACCP plan when required	0	3	0	105				
	Inadequate Cooking								
	Raw shell eggs broken for immediate service cooked to 145 °F (63								
4A	°C) for 15 seconds. Raw shell eggs broken but not prepared for immediate service cooked to155 °F (68 °C) for 15 seconds	4	1	21	82				
4B	Comminuted Fish, Meats, Game animals cooked to 155 °F (68 °C) for 15 seconds	7	1	26	74				
	Roasts, including formed roasts, are cooked to 130 °F (54 °C) for								
4C	112 minutes or as Chart specified and according to oven	3	0	15	90				
40	parameters per Chart Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,	3	U	13	90				
	stuffed ratites, or stuffing containing fish, meat, poultry or ratites								
4D 4E	cooked to 165 °F (74 °C) for 15 seconds	67	0	32	5 108				
46	Wild game animals cooked to 165 °F (74 °C) for 15 seconds Raw animal foods cooked in microwave are rotated, stirred,	0	U	0	106				
4F	covered, and heated to 165 °F (74 °C). Food is allowed to stand covered for 2 minutes after cooking	0	1	2	105				
4G	Pork, ratites, injected meats are cooked to 155 °F (68 °C) for 15 seconds.	15	1	29	63				
4H	All other PHF cooked to 145 °F (63 °C) for 15 seconds	11	0	34	63				
5A	PHF that is cooked and cooled on premises is rapidly reheated to 165 °F (74 °C) for 15 seconds for hot holding	9	1	33	65				
5B	Food reheated in a microwave is heated to 165 °F (74 °C) or higher	0	0	17	91				
5C	Commercially processed ready-to-eat food, reheated to 140 °F (60 °C) or above for hot holding	23	5	49	31				
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	0	0	12	96				

APPENDIX F – DELI DEPARTMENTS/STORES

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA					
Improper Holding/Time & Temperature										
6A	Cooked PHF 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	12	16	64	16					
6B	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F (5 °C) or below within 4 hours	7	6	47	48					
6C	Foods received at a temperature according to Law are cooled to 41 °F (5 °C) within 4 hours	8	1	44	55					
7A	PHF is maintained at 41 °F (5 °C) or below, except during preparation, cooking, cooling or when time is used as a public health control.	34	74	0	0					
8A	PHF 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.	38	59	6	5					
8B 9A	Roasts are held at a temperature of 130 °F (54 °C) or above Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)	30	2 51	12	92					
9B	Discard RTE PHF and/or opened commercial container exceeding 7 days at \leq 41 °F (5 °C) or 4 days at \leq 45 °F (7 °C)	21	27	56	4					
9C	Opened Commercial container of prepared ready-to-eat PHF is date marked as required	20	79	4	5					
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	2	0	4	102					
	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	84	21	0	3					
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	78	4	2	24					
10C 10D	Food is protected from environmental contamination – critical Items After being served or sold to a consumer, food is not re-served	94 32	14 0	0 40	0 36					
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	45	63	0	0					

APPENDIX F – DELI DEPARTMENTS/STORES

DATA									
ITEM	DATA ITEM	#	#	#	#				
#		IN	OUT	NO	NA				
Poor Personal Hygiene									
12A	Hands are clean and properly washed when and as required	44	58	6	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-	95	11	2	0				
13A	service or single-use articles								
	Employees do not contact exposed, ready-to-eat food with their bare			_					
14A	hands.	94	10	3	1				
15A	Handwash facilities conveniently located and accessible for Employees	84	24	0	0				
134	Handwash facilities supplied with hand cleanser/sanitary	04	24	U	U				
15B	towels/hand drying devices	87	21	0	0				
	Other/Chemical								
	If used, only approved food or color additives. Sulfites are not								
	applied to fresh fruits and vegetables intended for raw								
16A	Consumption	23	0	0	85				
	Poisonous or toxic materials, chemicals, lubricants, pesticides,								
460	medicines, first aid supplies, and other personal care items are	70	20	0	0				
16B	properly identified, stored and used Poisonous or toxic materials held for retail sale are properly stored	78	30	0	0				
16C	r distribus of toxic materials field for retail sale are properly stored	6	0	0	102				
	Supplemental Items – New Areas of Study								
17A	Pork is cooked to 145 °F (63 °C) or above for 15 seconds	16	0	29	63				
	Ratites and injected meats are cooked to 155 °- F (68 °C) for 15								
17B	seconds	2	0	33	73				
	PHF is maintained at 135 °F (57 °C) or above, except during								
404	preparation, cooking, or cooling or when time is used as a public	14	F.0	_	_				
18A	health control	41	56	6	5				
	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 Food Code.	18	90	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	1	0	107				
ZUA	After receiving, raw shell eggs are immediately placed under	0	<u>'</u>	U	107				
	refrigeration that maintains ambient air temperature of 45 °F (7 °C) or								
21A	less	6	3	17	82				

APPENDIX F - DELI DEPARTMENTS/STORES

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
22A	After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45 °F (7 °C) or less	18	3	4	83
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	108
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 Baseline 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	108
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	108

DATA ITEM	DATA ITEM	#	#	#	#				
#		IN	OUT	NO	NA				
Food From Unsafe Sources									
	All food from Regulated Food Processing Plants/No Home	400							
1A	prepared/canned foods All shellfish from NSSP listed sources. No recreationally caught	108	1	0	0				
1B	shellfish received or sold	11	3	0	95				
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	4	0	0	105				
	Food received at proper temperatures/protected from contamination								
2A	during transportation and receiving/food is safe, unadulterated	105	4	0	0				
3A	Shellstock tags/labels retained for 90 days from the data the container is emptied	2	3	6	98				
3B	As required, written documentation of parasite destruction maintained for 90 days for fish products	0	0	0	109				
3C	CCP monitoring records maintained in accordance with HACCP plan when required	0	1	0	108				
	Inadequate Cooking								
	Raw shell eggs broken for immediate service cooked to 145 °F (63								
4A	°C) for 15 seconds. Raw shell eggs broken but not prepared for	0	0	0	109				
4/4	immediate service cooked to 155 °F (68 °C) for 15 seconds Comminuted Fish, Meats, Game animals cooked to 155 °F (68 °C)	0	0	-	109				
4B	for 15 seconds	0	0	5	104				
	Roasts, including formed roasts, are cooked to 130 °F (54 °C) for								
4C	112 minutes or as Chart specified and according to oven parameters per Chart	0	0	1	108				
10	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,			-	100				
	stuffed ratites, or stuffing containing fish, meat, poultry or ratites				i				
4D	cooked to 165 °F (74 °C) for 15 seconds	1	1	3	104				
4E	Wild game animals cooked to 165 °F (74 °C) for 15 seconds Raw animal foods cooked in microwave are rotated, stirred,	0	0	0	109				
	covered, and heated to 165 °F (74 °C). Food is allowed to stand								
4F	covered for 2 minutes after cooking	0	0	0	109				
40	Pork, ratites, injected meats are cooked to 155 °F (68 °C) for 15	_		_	404				
4G 4H	seconds. All other PHF cooked to 145 °F (63 °C) for 15 seconds	0	0	5 5	104 104				
40	PHF that is cooked and cooled on premises is rapidly reheated to	U	U		104				
5A	165 °F (74 °C) for 15 seconds for hot holding	0	0	0	109				
5B	Food reheated in a microwave is heated to 165 °F (74 °C) or higher	0	0	0	109				
	Commercially processed ready-to-eat food, reheated to 140 °F				400				
5C	(60 °C) or above for hot holding	0	0	0	109				
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	0	0	0	109				

DATA	\(\text{\tint{\text{\tin}\text{\ti}\\\ \text{\text{\text{\text{\text{\text{\text{\text{\tin}\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\text{\ti}\text{\texi}\text{\text{\text{\text{\text{\text{\text{\text{\texi\tin}\tint{\texi}\tint{\text{\texi}\tint{\ti}\tint{\text{\texi}\tinz{\text{\texi}\tinz{\text{\ti}								
ITEM	DATA ITEM	#	#	#	#				
#		IN	OUT	NO	NA				
Improper Holding/Time & Temperature									
	Cooked PHF is cooled from 140 °F (60 °C) to 70 °F (21 °C)								
C A	within 2 hours and from 140 °F (60 °C) to 41 °F (5 °C) or below	0			405				
6A	within 6 hours	0	1	3	105				
6B	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F (5 °C) or below within 4 hours	2	0	6	101				
05	Foods received at a temperature according to Law are cooled to 41		-		101				
6C	°F (5 °C) within 4 hours	1	0	13	101				
	PHF 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.	90	19	0	0				
8A	PHF is maintained at 140 °F (60 °C) or above, except during preparation, cooking, or cooling or when time is used as a public								
UA.	health control.	0	2	5	102				
8B	Roasts are held at a temperature of 130 °F (54 °C) or above	0	0	0	109				
	Ready-to-eat PHF held for more than 24 hours is date marked as								
9A	required (prepared on-site)	7	9	0	93				
0.0	Discard RTE PHF and/or opened commercial container	0	_		00				
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 is date	8	5	14	82				
9C	marked as required	5	12	3	89				
	When time only is used as a public health control, food is cooked		12		- 00				
9D	and served within 4 hours as required	0	0	1	108				
	Contaminated Equipment/Protection from Contam	ninati	ion						
	Food is protected from cross contamination by separating raw								
464	animal foods from raw ready-to-eat food and by separating raw	C4	20		20				
10A	animal foods from cooked ready-to-eat food Raw animal foods are separated from each other during storage,	61	26	0	22				
10B	preparation, holding, and display	81	26	0	2				
	Food is protected from environmental contamination – critical items								
10C	·	100	9	0	0				
10D	After being served or sold to a consumer, food is not re-served	26	0	23	60				
110	Food-contact surfaces and utensils are clean to sight and touch and	62	46	_	_				
11A	sanitized before use	63	46	0	0				

DATA	DATA COMMANT (page 6 of 4)								
DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA				
Poor Personal Hygiene									
12A	Hands are clean and properly washed when and as required	53	31	25	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	78	7	24	0				
13A	single-service or single-use articles								
	Employees do not contact exposed, ready-to-eat food with their bare								
14A	hands.	35	3	24	47				
15A	Handwash facilities conveniently located and accessible for Employees	86	23	0	0				
134	Handwash facilities supplied with hand cleanser/sanitary	00	20	0					
15B	towels/hand drying devices	82	27	0	0				
	Other/Chemical		•						
	If used, only approved food or color additives. Sulfites are not								
	applied to fresh fruits and vegetables intended for raw								
16A	Consumption	10	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	90	19	0	0				
100	Poisonous or toxic materials held for retail sale are properly stored	90	19	U	U				
16C	Tologrado di toxio materialo nela for retali sale are property storea	3	1	0	105				
	Supplemental Items – New Areas of Study								
17A	Pork is cooked to 145 °F (63 °C) or above for 15 seconds	0	0	5	104				
	Ratites and injected meats are cooked to 155 °F (68 °C) for 15								
17B	seconds	0	0	5	104				
	PHF is maintained at 135 °F (57 °C) or above, except during								
18A	preparation, cooking, or cooling or when time is used as a public health control	1	1	5	102				
10/4	Facility has a written policy that is consistent with 2-201 of the <i>Food</i>	<u>'</u>	'		102				
	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								
404	employee responsibility to notify management of symptoms and	40	24	_					
19A	illnesses identified in the <i>Food Code</i> . When packaged in a food establishment, juice is treated under a	18	91	0	0				
	HACCP Plan to reduce pathogens or be labeled as specified in the								
20A	Food Code	0	0	0	109				
	After receiving, raw shell eggs are immediately placed under								
	refrigeration that maintains ambient air temperature of 45 °F (7 °C) or								
21A	less	2	1	2	104				

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
22A	After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45 °F (7 °C) or less	4	1	0	104
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	109
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 Baseline 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	109
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	109

DATA SUMMART (page 1 of 4)								
DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA			
	Food From Unsafe Sources							
4.4	All food from Regulated Food Processing Plants/No Home	404						
1A	prepared/canned foods All shellfish from NSSP listed sources. No recreationally caught	104	1	0	0			
1B	shellfish received or sold	75	3	0	27			
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	0	0	0	105			
	Food received at proper temperatures/protected from contamination							
2A	during transportation and receiving/food is safe, unadulterated	103	2	0	0			
3A	Shellstock tags/labels retained for 90 days from the data the container is emptied	39	31	4	31			
3B	As required, written documentation of parasite destruction maintained for 90 days for fish products	2	6	0	97			
3C	CCP monitoring records maintained in accordance with HACCP plan when required	0	4	0	101			
	Inadequate Cooking							
	Raw shell eggs broken for immediate service cooked to 145 °F (63							
4A	°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	105			
4B	Comminuted Fish, Meats, Game animals cooked to 155 °F (68 °C) for 15 seconds	0	0	2	103			
	Roasts, including formed roasts, are cooked to 130 °F							
4C	(54 °C) for 112 minutes or as Chart specified and according to oven parameters per Chart	0	0	0	105			
	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	3	102			
4E	Wild game animals cooked to 165 °F (74 °C) for 15 seconds	0	0	0	105			
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	2	103			
4G	Pork, ratites, injected meats are cooked to 155 °F (68 °C) for 15 seconds.	0	0	0	105			
4H	All other PHF cooked to 145 °F (63 °C) for 15 seconds	4	0	49	52			
5A	PHF that is cooked and cooled on premises is rapidly reheated to 165 °F (74 °C) for 15 seconds for hot holding	0	1	0	104			
5B	Food reheated in a microwave is heated to 165 °F (74 °C) or higher	0	0	0	105			
5C	Commercially processed ready-to-eat food, reheated to 140 °F (60 °C) or above for hot holding	1	1	2	101			
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	0	0	0	105			

DATA	DATA COMMANT (page 2 of 4)							
DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA			
Improper Holding/Time & Temperature								
	Cooked PHF is cooled from 140 °F (60 °C) to 70 °F (21 °C)							
6A	within 2 hours and from 140 $^{\circ}$ F (60 $^{\circ}$ C) to 41 $^{\circ}$ F (5 $^{\circ}$ C) or below within 6 hours	1	1	18	85			
6B	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F (5 °C) or below within 4 hours	3	2	15	85			
6C	Foods received at a temperature according to Law are cooled to 41 °F (5 °C) within 4 hours	8	0	45	52			
7A	PHF is maintained at 41 °F (5 °C) or below, except during preparation, cooking, cooling or when time is used as a public health control.	88	17	0	0			
8A	PHF 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.	3	3	1	98			
8B	Roasts are held at a temperature of 130 °F (54 °C) or above	0	0	0	105			
9A	Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)	7	18	2	78			
9B	Discard RTE PHF and/or opened commercial container exceeding 7 days at ≤ 41 °F (5 °C) or 4 days at ≤ 45 °F (7 °C)	9	9	53	34			
9C	Opened Commercial container of prepared ready-to-eat PHF is date marked as required	10	45	11	39			
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	1	0	1	103			
	Contaminated Equipment/Protection from Contam	inati	ion					
	Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods							
10A	from cooked ready-to-eat food	75	23	3	4			
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	72	16	0	17			
10C	Food is protected from environmental contamination – critical Items	97	8	0	0			
10D	After being served or sold to a consumer, food is not re-served	23	0	26	56			
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	68	37	0	0			

DATA	DATA COMMINITY (page 6 01 4)							
ITEM	DATA ITEM	#	#	#	#			
#		IN	OUT	NO	NA			
Poor Personal Hygiene								
12A	Hands are clean and properly washed when and as required	48	29	28	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	82	7	16	0			
13A	single-service or single-use articles							
	Employees do not contact exposed, ready-to-eat food with their bare	00	_	0.5	4.5			
14A	hands. Handwash facilities conveniently located and accessible for	60	5	25	15			
15A	employees	89	16	0	0			
10/1	Handwash facilities supplied with hand cleanser/sanitary	- 00	10		Ů			
15B	towels/hand drying devices	88	17	0	0			
	Other/Chemical							
	If used, only approved food or color additives. Sulfites are not							
	applied to fresh fruits and vegetables intended for raw				0.4			
16A	consumption Poisonous or toxic materials, chemicals, lubricants, pesticides,	11	0	0	94			
	medicines, first aid supplies, and other personal care items are							
16B	properly identified, stored and used	85	20	0	0			
	Poisonous or toxic materials held for retail sale are properly stored							
16C		3	1	0	101			
	Supplemental Items – New Areas of Study		1		ı			
17A	Pork is cooked to 145 °F (63 °C) or above for 15 seconds	0	0	0	105			
47D	Ratites and injected meats are cooked to 155 °F (68 °C) for 15	0	0	0	105			
17B	seconds DHE is maintained at 125 °E (E7 °C) or above, except during	0	U	U	105			
	PHF is maintained at 135 °F (57 °C) or above, except during preparation, cooking, or cooling or when time is used as a public							
18A	health control	3	3	1	98			
	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> .	17	88	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	105			
	After receiving, raw shell eggs are immediately placed under							
21A	refrigeration that maintains ambient air temperature of 45 °F (7 °C) or less	0	0	0	105			
41A	1000	J	U	U	100			

DATA	271171 6 5 11111 (10 11 19 11 11 11 11 11 11 11 11 11 11 11				
DATA	DATA ITEM				.,
ITEM	DATA ITEM	#	#	#	#
#		IN	OUT	NO	NA
	Supplemental Items – New Areas of Study (cont.))			
	After receipt, raw shell eggs are stored in refrigerated				
	equipment that maintains ambient air temperature of 45 °F (7 °C) or				
22A	less	0	0	0	105
	Prepackaged juice/beverage containing juice with a warning label (21				
23A	CFR, Section 101.17(g)) not served	0	0	0	105
	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				
	Baseline Form), unless cooked to order & immediately				
	served; broken immediately before baking and thoroughly cooked;				
	or included as an ingredient for a recipe supported				
23B	by a HACCP plan that controls Salmonella Enteritidis	0	0	0	105
	Raw or partially cooked animal food and raw seed sprouts not served				
23C		0	1	0	104

DATA SOMMAKT (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	407						
1A	prepared/canned foods All shellfish from NSSP listed sources. No recreationally caught	107	1	0	0			
1B	shellfish received or sold	0	0	0	108			
1C	Game, wild mushrooms harvested with approval of Regulatory Authority	4	0	1	103			
	Food received at proper temperatures/protected from contamination							
2A	during transportation and receiving/food is safe, unadulterated	105	3	0	0			
3A	Shellstock tags/labels retained for 90 days from the data the container is emptied	1	0	0	107			
3B	As required, written documentation of parasite destruction maintained for 90 days for fish products	1	0	0	107			
3C	CCP monitoring records maintained in accordance with HACCP plan when required	1	0	0	107			
	Inadequate Cooking							
	Raw shell eggs broken for immediate service cooked to 145 °F (63							
4A	°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	108			
	Comminuted Fish, Meats, Game animals cooked to 155 °F (68 °C)							
4B	for 15 seconds	0	0	0	108			
	Roasts, including formed roasts, are cooked to 130 °F							
4C	(54 °C) for 112 minutes or as Chart specified and according to oven parameters per Chart	0	0	0	108			
	Poultry; stuffed fish, stuffed meat, stuffed pasta, stuffed poultry,							
4D	stuffed ratites, or stuffing containing fish, meat, poultry or ratites	0	0	0	108			
4E	cooked to 165 °F (74 °C) for 15 seconds Wild game animals cooked to 165 °F (74 °C) for 15 seconds	0	0	0	108			
	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	0	0	0	108			
4G	Pork, ratites, injected meats are cooked to 155 °F (68 °C) for 15 seconds.	0	0	0	108			
4H	All other PHF cooked to 145 °F (63 °C) for 15 seconds	0	0	0	108			
5 A	PHF that is cooked and cooled on premises is rapidly reheated to	_	_	2	105			
5A	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	3	105			
5B	, ,	0	0	2	106			
5C	Commercially processed ready-to-eat food, reheated to 140 °F (60 °C) or above for hot holding	1	0	5	102			
5D	Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters	0	0	0	108			

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Improper Holding/Time & Temperature)			
6A	Cooked PHF is cooled from 140 °F (60 °C) to 70 °F (21 °C) within 2 hours <u>and</u> from 140 °F (60 °C) to 41 °F (5 °C) or below within 6 hours	0	0	6	102
6B	PHF (prepared from ingredients at ambient temperature) is cooled to 41 °F (5 °C) or below within 4 hours	5	4	21	78
6C	Foods received at a temperature according to Law are cooled to 41 °F (5 °C) within 4 hours	0	0	11	97
7A	PHF is maintained at 41 °F (5 °C) or below, except during preparation, cooking, cooling or when time is used as a public health control.	31	73	0	No PHFs 4
8A	PHF 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.	6	0	0	102
8B	Roasts are held at a temperature of 130 °F (54 °C) or above	0	0	0	108
9A	Ready-to-eat PHF held for more than 24 hours is date marked as required (prepared on-site)	31	16	5	56
9B	Discard RTE PHF and/or opened commercial container exceeding 7 days at \leq 41 °F (5 °C) or 4 days at \leq 45 °F (7 °C)	26	3	28	51
9C	Opened Commercial container of prepared ready-to-eat PHF is date marked as required	3	3	3	99
9D	When time only is used as a public health control, food is cooked and served within 4 hours as required	0	0	0	108
	Contaminated Equipment/Protection from Co	ontan	ninatio	n	
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	18	2	0	88
10B	Raw animal foods are separated from each other during storage, preparation, holding, and display	9	0	0	99
10C	Food is protected from environmental contamination – critical items	102	6	0	0
10D	After being served or sold to a consumer, food is not reserved	28	0	21	59
11A	Food-contact surfaces and utensils are clean to sight and touch and sanitized before use	60	48	0	0

DATA	DATA GOMMANT (page 6 of 4)							
ITEM	DATA ITEM	#	#	#	#			
#		IN	OUT	NO	NA			
Poor Personal Hygiene								
12A	Hands are clean and properly washed when and as required	20	10	78	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	40	8	60	0			
13A	single-service or single-use articles	.0						
	Employees do not contact exposed, ready-to-eat food with their bare							
14A	hands.	27	4	74	3			
45.	Handwash facilities conveniently located and accessible for							
15A	employees	79	28	0	0			
15B	Handwash facilities supplied with hand cleanser/sanitary towels/hand drying devices	85	22	0	0			
100	Other/Chemical	00		Ü	Ü			
	If used, only approved food or color additives. Sulfites are not							
	applied to fresh fruits and vegetables intended for raw							
16A	consumption	10	0	0	98			
	Poisonous or toxic materials, chemicals, lubricants, pesticides,							
	medicines, first aid supplies, and other personal care items are							
16B	properly identified, stored and used	87	21	0	0			
16C	Poisonous or toxic materials held for retail sale are properly stored	57	3	0	48			
	Supplemental Items – New Areas of Study	Ů.	Ū	Ü				
17A	Pork is cooked to 145 °F (63 °C) or above for 15 seconds	0	0	0	108			
	Ratites and injected meats are cooked to 155 °F (68 °C) for 15							
17B	seconds	0	0	0	108			
	PHF is maintained at 135 °F (57 °C) or above, except during							
	preparation, cooking, or cooling or when time is used as a public							
18A	health control	6	0	0	102			
	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> .	18	90	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	1	1	1	105			
	After receiving, raw shell eggs are immediately placed under							
21A	refrigeration that maintains ambient air temperature of 45 °F (7 °C) or less	1	0	13	94			
ZIA	1000	· ·	U	13	34			

DATA ITEM #	DATA ITEM	# IN	# OUT	# NO	# NA
	Supplemental Items – New Areas of Study (cont.))			
22A	After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45 °F (7 °C) or less	11	4	0	93
23A	Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served	0	0	0	108
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 Baseline 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	108
23C	Raw or partially cooked animal food and raw seed sprouts not served	0	0	0	108

APPENDIX J – DIRECTORY

FDA NATIONAL RETAIL FOOD TEAM (page 1 of 6)

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APPENDIX J – DIRECTORY

FDA NATIONAL RETAIL FOOD TEAM (page 2 of 6)

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FDA NATIONAL RETAIL FOOD TEAM (page 3 of 6)

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APPENDIX K – RESOURCES

WEB SITE LOCATIONS FOR REFERENCED DOCUMENTS

1997 FDA Food Code

www.cfsan.fda.gov/~dms/fc-toc.html

2001 FDA Food Code

www.cfsan.fda.gov/~dms/fc01-toc.html

2003 Supplement to the 2001 FDA Food Code

www.cfsan.fda.gov/~dms/fc01-su2.html

FDA Voluntary National Retail Food Regulatory Program Standards

www.cfsan.fda.gov/~dms/ret-toc.html

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 HACCP Principles Guide for Operators of</u> Establishments at the Retail Level

www.cfsan.fda.gov/~dms/hret-toc.html

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

* Not available on the FDA web site at the time of printing. A copy can be obtained by contacting one of the FDA Regional Retail Food Specialists listed in Appendix J

Reinventing Food Regulations (1996), National Performance Report

http://govinfo.library.unt.edu/npr/library/rsreport/foodreg.html

Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000)

www.cfsan.fda.gov/~dms/retrsk.html

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

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