



Oregon Risk Factor Study #2 2009-2011

Oregon Foodborne Illness Prevention Program Second Statewide Assessment of Foodborne Illness Risk Factors in Restaurants

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ABSTRACT

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. Oregon followed suit in 2002-2003 by being the first jurisdiction in the nation to complete their statewide baseline study.

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, Oregon hopes to evaluate trends and determine whether progress is being made toward the goals of reducing the occurrence of foodborne illness risk factors. 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.

In order to measure Oregon's progress against the FDA retail food program goal, an assessment of the current status of the occurrence of foodborne illness risk factors is required. Although the level of foodborne illnesses would be the ideal food program performance indicator, the occurrence of foodborne illness is underreported, making it an unreliable program measurement. As an alternative, the occurrence of foodborne illness risk factors was selected by the Food and Drug Administration (FDA) as the performance indicator.

These foodborne illness risk factors are:

- Food from Unsafe Sources;
- Inadequate Cooking;
- Improper Holding Temperature;
- Contaminated Equipment; and
- Poor Personal Hygiene.

In 2009, Oregon began its second Risk Factor Study to collect more information about gaps in the state's food safety system. This report presents the methodology used to establish a risk factor study and reports the results of the data collected. For the rest of the report the project will be referred to as the *Oregon Risk Factor Study*. 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.

The first report was issued in 2003 with an extension granted by the FDA to start the second study a year late, in 2009. Because contractors and FDA partnership grants were used for the data collection, the work was staggered across two years and completed in 2011. Oregon's third data collection study is scheduled for 2016.

Based on results from Oregon's 2003 Baseline Study, the Oregon Health Authority (OHA) chose to focus on improving handwashing in restaurant facilities. Based on data from Aimee Pragle, MS¹ and Donna Beegle, PhD², several interventions were introduced, from increasing the criticality of soap and paper towels at a hand sink, to the development of the innovative Handwashing Legends Project in 2007. For more specifics on this innovative project, see our website at:

<http://public.health.oregon.gov/HealthyEnvironments/FoodSafety/Pages/hlp.aspx>. The Handwashing Legends materials were a model for the FDA Oral Learner Culture project and they now have several materials online as well at:
<http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm212661.htm> .

For each facility type, 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 many of the same risk factors and data items identified as problem areas in the 2003 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 potentially hazardous foods (PHF) and commercial foods.

Within the poor personal hygiene risk factor, the proper handwashing data item and the eating/drinking in designated areas had the highest percent Out of Compliance value for both facility types.

¹ Aimee S. Pragle, M.S., Anna K. Harding, Ph.D., R.S., and James C. Mack, M.P.A., R.E.H.S., Food Workers' Perspectives on Handwashing Behaviors and Barriers in the Restaurant Environment, Journal of Environmental Health, June 2007, Volume 69, No. 10

² Donna Beegle, Oregon Environmental Health Specialist Network (EHS-Net) Communication Study, www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm119616.pdf

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.

The FDA 1997 Food Code was the standard of measurement used for this project. The FDA *Baseline Data Collection Form* reflecting Food Code provisions was used for collecting data on the occurrence of the 5 risk factors in Oregon. The *FDA Retail Food Program Database of Foodborne Illness Risk Factors* report was the guidance document for Oregon's project.

OHA followed the FDA model, using identical data collection tools and standardized staff. Data for the baseline were obtained from 174 total assessments of restaurants, consisting of 3,894 observations, conducted by contract staff that were trained by OHA staff for consistency.

The resulting data was analyzed using several approaches to determine practices and behaviors needing priority attention. Because Oregon has seen such an improvement, only Prevention of Hand Contamination (bare hand contact prohibition, which is not required under Oregon law), PHF Held Cold at 41F (5C) or below, RTE, PHF Date Marked After 24 hours; and Proper, Adequate Handwashing exceeded 30% OUT OF COMPLIANCE observation rate in both fast food and full service restaurants. However, there are some practices that have 20% out of compliance rate worth addressing:

- Commercially Processed RTE, PHF Date Marked;
- Employees Eating/Drinking in Food Areas;
- Food Protected from Environmental Contamination; and
- Surfaces/Utensils Cleaned/Sanitized.

In order to improve the safety of food at the retail level, the food industry and the regulatory community must remain focused in their efforts to reduce the individual data items having the most significant OUT OF COMPLIANCE observations. Interventions will not be developed at this time for Prevention of Hand Contamination because of the differences between the Oregon Food Code and the 1997 FDA Food Code.

The improvement goals for the 2009-2011 Risk Factor Study were to reach 81% in compliance overall for fast food restaurants and 75% for full service restaurants, which were reached, with 82% in compliance overall for fast food restaurants and 77% for full service restaurants.

I. BACKGROUND

The Oregon Health Authority (OHA) conducted their baseline risk factor study in 2002-2003 and created interventions around handwashing as a result. The second risk factor study was conducted to start looking for patterns and trends in the Oregon food safety system as a whole.

The level of foodborne illnesses would be the ideal food program performance indicator. The occurrence of foodborne illness is grossly underreported, which makes it an unreliable program measurement. As an alternative, the occurrence of foodborne illness risk factors (risk factors) was selected as the performance indicator. Based on the Centers for Disease Control and Prevention (CDC) Surveillance Report for 1988 – 1992, five broad categories of risk factors contributing to foodborne illness were identified. The identified risk factors include:

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

For the Oregon Baseline, OHA used identical data collection tools to the FDA model and standardized staff. Data for the baseline were obtained from 174 total assessments of restaurants, consisting of 3,894 observations, conducted by OHA staff.

This report presents the methodology used to establish the second Oregon Risk Factor Study and reports the results of the data collected. The report is provided to regulators and industry with the expectation that it will be used to focus greater attention and increased resources on the control of risk factors.

II. INTRODUCTION AND PURPOSE

The initiative to create the *Oregon Food Program Database of Foodborne Illness Risk Factors in Restaurants* began in December 2002, and is ongoing. The project's purpose is to establish a baseline against which industry and regulatory efforts to change behaviors and practices directly related to foodborne illness will be measured in Oregon. It recognizes the need to fill a void that currently exists in the assessment of program effectiveness for controlling these risk factors. The information gathered will also contribute to the FDA nationwide baseline database.

By establishing a second data point with this study, the information gathered from future studies can be used to measure trends in compliance with specific requirements of the Food Code. It is expected that an improvement in compliance with the Food Code provisions that address these risk factors will have a direct impact on the occurrence of foodborne illness.

The 1997 FDA Food Code was the standard of measurement used during the baseline assessments. It is important to note that the baseline data collection was not designed to determine an individual establishment's compliance with state requirements. OHA followed the FDA model, using the same forms and assessment practices.

III. METHODOLOGY

A. Selection of Facility Types

In Oregon, OHA has jurisdiction over food service facilities and not the other categories included in the FDA risk factor studies, so only full-service and fast food restaurants were included. Based on information from FDA statisticians, 87 assessments were needed for each facility type in order for the results to be statistically significant.

B. Selection of Data Collectors

One FDA-standardized staff and four county inspection staff that have been state-standardized were utilized to ensure consistency in the data collection process.

C. Selection of Facilities Statewide

All facilities for the study were drawn from a statewide list of licensed facilities using a random number table. Each county separated the facilities in their area into the categories of full service or fast food.

Inclusion of establishments focused on those operations that:

- Involved extensive handling of ingredients; or
- Conducted a variety of food preparation processes.

The Food Code divides food establishments into 5 risk type categories. The Risk Categorization of Food Establishments, contained in Annex 4 of the Food Code is presented in the table that follows. The establishments described above generally fall into risk type categories 3, 4, or 5 based on their operational practices and populations served.

RISK CATEGORIZATION OF FOOD ESTABLISHMENTS

RISK TYPE	RISK TYPE CATEGORY DESCRIPTION
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.

All of the facility types included in this study were in risk type categories 3, 4, and 5.

In order to preserve data reliability and to assure confidentiality of the selected establishments, observations have been entered into the database by number rather than by establishment name or location.

D. Risk Factor Study Data Collection Procedure

The 5 major risk factors contributing to foodborne illness identified by CDC provided the foundation for the data collection assessment form. For each risk factor, Food Code requirements were identified and grouped into individual data items on the assessment form (see Baseline Data Collection Reference Sheet, Appendix A). An additional risk factor, "Other", was used to capture the potential food safety risks related to possible contamination by toxic or unapproved chemicals in the establishment.

E. Risk Factor Study Data Collection Form

The Baseline Data Collection assessment form (see Appendix B) used in this project contained 44 individual data items. Forty-two (42) of the 44 individual data items were actual provisions of the Food Code. Two items (1D, 13B) were outside the parameters of the 1997 Food Code, but were items of interest in Oregon. These two data items were not included in the analysis of the baseline data because they were not requirements of the 1997 Food Code.

For each of the 44 observations, OHA staff determined whether the item was:

- **IN** = Item found IN COMPLIANCE with Food Code provisions.
- **OUT** = Item found OUT OF COMPLIANCE with Food Code provisions. An explanation was provided in the comment section on the data collection form for each OUT OF COMPLIANCE observation.
- **N.O.** = Item was NOT OBSERVED. The N.O. notation was used when an item was a usual practice in the food service operation, but the practice was not observed during the time of the assessment.
- **N.A.** = Item was NOT APPLICABLE. The N.A. notation was used when an item was not part of the food service operation.

The same data collection form was used at each establishment. The data collected for each of the 2 facility types consist of about 174 reports, each with 44 items scored either "IN", "OUT", "N.O.", or "N.A."

Unannounced visits to the selected establishments were designed to be observational rather than regulatory. A representative of the county, having regulatory oversight responsibilities for the establishments, usually accompanied OHA staff or contractors. If conditions observed merited regulatory actions the accompanying local representative could intervene to ensure appropriate corrective actions were taken. If no local representative accompanied OHA staff, then the staff informed the operator of any violations observed during the assessment as a courtesy.

The completed data collection assessment forms are stored at the OHA main office in Portland for entry into a central database provided by FDA. Before analyzing the data, a thorough review of the data collection forms was conducted to ensure reporting consistency within the established project design.

IV. DATA REPORTS AND DISCUSSION

The results of the 2009-2011 *Oregon Risk Factor Study* are presented in 5 parts:

- A. Overall percent (%) of observable and applicable data items observed IN COMPLIANCE for each facility type and the FDA Improvement Goal (Table 1).
- B. Percent (%) of total observations IN COMPLIANCE for each of the facility types for controlling the risk factors (Table 2).
- C. Individual data items needing priority attention for each of the facility types (Tables 3, 4).
- D. Series of figures illustrating the percent breakdown of the most significant OUT OF COMPLIANCE data items observed for each of the facility types (Figures 1 through 10).
- E. Summary of the most significant OUT OF COMPLIANCE data items (Figure 11).

A. Overall Percent (%) of observable and applicable data items observed IN COMPLIANCE for each facility type and the improvement goal

The data presented in **Table 1** reflect the TOTAL of all data items found to be IN COMPLIANCE and the established FDA improvement goal. This figure should NOT be used as an indicator of the percentage of establishments IN or OUT OF COMPLIANCE.

Table 1. TOTAL PERCENT (%) of All Data Items found IN COMPLIANCE and the FDA Improvement Goal, for Each Facility Type

		<u>Oregon Risk Factor Study Baseline 2003*</u> % IN COMPLIANCE Observable Items (rounded to nearest %)	FDA 10-Year Improvement Goal Target (rounded to nearest %)	<u>Oregon Risk Factor Study 2011*</u> % IN COMPLIANCE Observable Items (rounded to nearest %)
Restaur- ants	Fast Food	74%	81%	82%
	Full- Service	67%	75%	77%

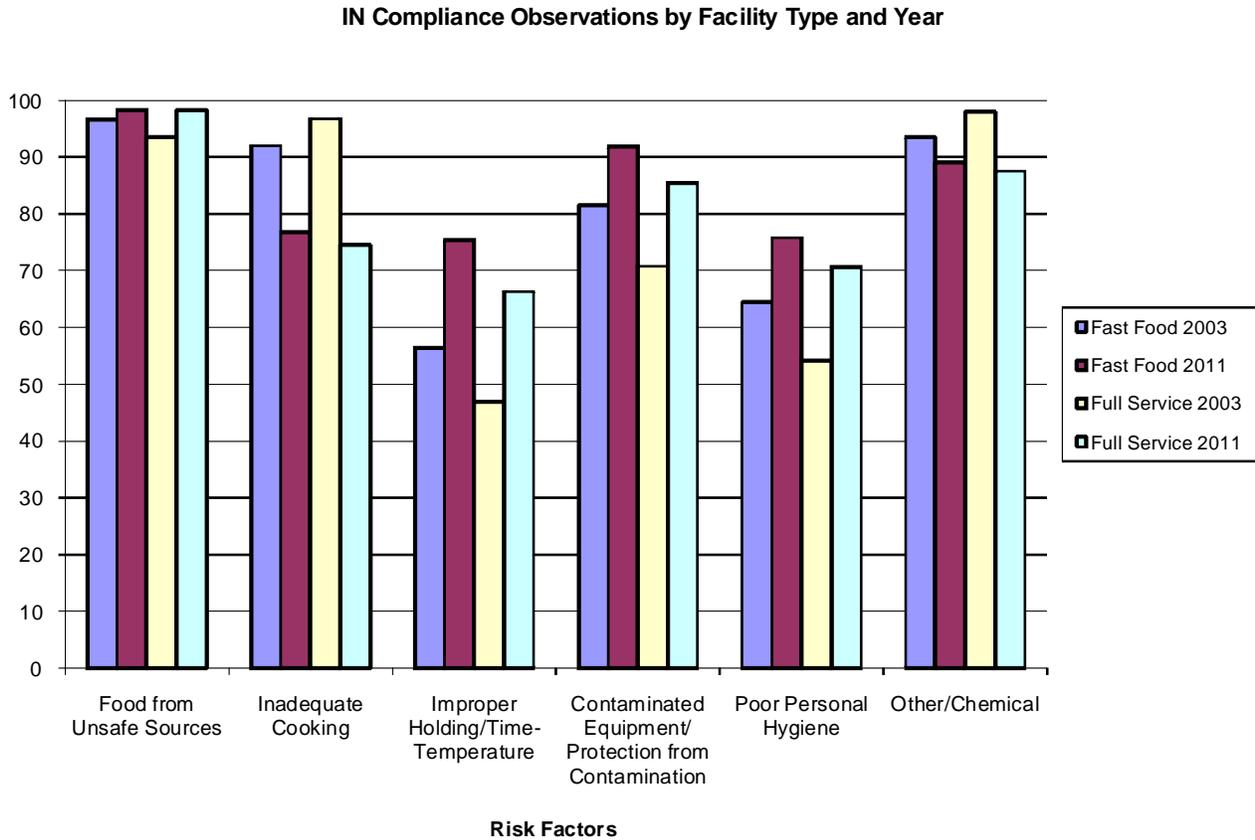
***2003 Baseline calculation:**

$$\text{Percent IN COMPLIANCE} = \frac{\text{All applicable, observable, IN COMPLIANCE data items within all risk factor categories}}{\text{Total number of observations}}$$

B. Percent (%) of total IN COMPLIANCE observations for controlling foodborne disease risk factors

Table 2 provides the percent of IN COMPLIANCE observations for each facility type as they pertain to controlling the 5 risk factors contributing to foodborne illness. Another risk factor, "Other," is included to collect data on food safety risks associated with the storage and use of chemicals.

Table 2. IN COMPLIANCE OBSERVATIONS WITH RESPECT TO CONTROLLING THE RISK FACTORS, BY FACILITY TYPE



C. Individual Data Items Needing Priority Attention

In order to enhance industry's managerial control and to focus regulatory intervention strategies on the reduction of OUT OF COMPLIANCE observations, both regulators and industry need to know what specific aspects are most in need of improvement. Tables 3 and 4 highlight individual data items with the highest number of OUT OF COMPLIANCE observations.

Some data items were not observed in significant numbers to support a valid interpretation. In order to determine which data items had too few observations for valid interpretation, several protocols were considered.

The protocol that was selected and used centered on various cutoff points using the raw number of OUT OF COMPLIANCE observations for each particular data item. The intent was to give equal emphasis to data items that had the same numbers of OUT OF COMPLIANCE observations, regardless of the facility type. In making such distinctions, it is preferable to stop at a cutoff point that has a very few or no data items just below that cutoff point. The OUT OF COMPLIANCE number that appeared to best provide a cutoff for establishing data item priorities for each of the facility types in our original baseline study was "28". As a result, the lists of individual data items for each facility type includes all specific data items that had 28 or more OUT OF COMPLIANCE observations. However, because so many items had a lower OUT OF COMPLIANCE rate for the 2011 risk factor study, cutoffs of "14" for fast food and "20" for full service were the best choices (in future data collections, a different cutoff number might be used).

This protocol resulted in different numbers of priority data items being identified for each facility type. For each facility type, the individual data items were sorted from the highest to the lowest OUT OF COMPLIANCE percentage.

Abbreviations used in the graphic presentation of the data in Tables 3 and 4:

C	Celsius
D	Day
F	Fahrenheit
HR	Hour
ID	Identified
PHF	Potentially Hazardous Food
RTE	Ready-to-eat

Tables 3 and 4. Percent (%) OUT OF COMPLIANCE Observations of individual data items needing priority attention

(A listing by Facility Type of individual data items having 14 (fast) or 20 (full service) or more raw number (N) OUT OF COMPLIANCE observations).

**Table 3. RESTAURANTS -- FAST FOOD
% OUT OF COMPLIANCE OBSERVATIONS**

Industry Segment -- Restaurants Facility Type -- Fast Food	N	Total Observations 2011	% OUT of COMPLIANCE 2011	N	Total Observations 2003	% OUT of COMPLIANCE 2003
Prevention of Hand Contamination	50	79	63%	67	79	85%
PHF Held Cold at 41F (5C) or Below	23	89	26%	44	87	51%
RTE, PHF Date Marked After 24 Hr	19	72	26%	48	82	59%
Employee Eating/Drinking	19	80	24%	NA	NA	NA
Commercially Processed RTE, PHF Date Marked	16	78	20%	50	80	63%
Food Protected from Environmental Contamination	16	89	18%	29	87	33%
Proper, Adequate Handwashing	14	80	18%	41	84	49%

**Table 4. RESTAURANTS -- Full-Service
% OUT OF COMPLIANCE Observations**

Industry Segment -- Restaurants Facility Type -- Full-Service	N	Total Observations 2011	% OUT of COMPLIANCE 2011	N	Total Observations 2003	% OUT of COMPLIANCE 2003
Prevention of Hand Contamination	64	83	77%	82	84	98%
PHF Held Cold at 41F (5C) or Below	31	87	36%	60	87	69%
Commercially Processed RTE, PHF Date Marked	NA	NA	NA	59	80	74%
RTE, PHF Date Marked After 24 Hr	26	79	33%	56	85	66%
Proper, Adequate Handwashing	23	77	30%	54	86	63%
Employee Eating/Drinking	22	82	27%	NA	NA	NA
Protected From Environmental Contamination	21	87	24%	37	87	43%
RTE, PHF held for 41F for 7 days is discarded as required	20	65	31%	NA	NA	NA
Surfaces/Utensils Clean/Sanitized	NA	NA	NA	34	87	39%
Raw/RTE Foods Separated	NA	NA	NA	32	84	38%

D. Percent (%) Breakdown of the Most Significant OUT OF COMPLIANCE Data Items Observed, Per Facility Type for 2011 Risk Factor Study

The CDC-identified risk factors contributing to foodborne illness apply to all retail-level food establishments. Each risk factor is composed of several individual data items (Food Code requirements) that are used to evaluate performance within retail facilities. This discussion will address each risk factor and the corresponding data items as they affect each of the facility types.

Figures 1-10 focus the analysis of the data on OUT OF COMPLIANCE observations as a percentage of the total number of observations for each risk factor or individual data item. This formula illustrates this comparison:

$$\frac{\text{TOTAL NUMBER OF OUT OF COMPLIANCE OBSERVATIONS}}{\text{TOTAL NUMBER OF OBSERVATIONS (BOTH IN AND OUT)}}$$

In an effort to identify and quantify the impact of each individual data item on the OUT OF COMPLIANCE percentage per risk factor for each of the facility types, a comparison of the relationship between the OUT OF COMPLIANCE individual data items was conducted. The following formula illustrates this comparison:

$$\frac{\text{TOTAL NUMBER OF OUT OF COMPLIANCE OBSERVATIONS/DATA ITEM/FACILITY}}{\text{TOTAL NUMBER OF OUT OF COMPLIANCE OBSERVATIONS/RISK FACTOR/FACILITY}}$$

For example, if 50 of 100 observations of the Poor Personal Hygiene risk factor were OUT OF COMPLIANCE and 30 of the 50 were attributable to the Prevention of Hand Contamination data item, then 60% of the OUT OF COMPLIANCE observations were attributable to Prevention of Hand Contamination. These relationships are shown in the following figures. Each figure demonstrates the relative significance of the various data items for that facility type.

Of the 5 CDC-identified risk factors on this Reference Sheet, the three that had data items with 14 (fast) or 20 (full) or more OUT OF COMPLIANCE OBSERVATIONS for full service and fast food restaurants were:

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

Data are graphically displayed in 2 formats:

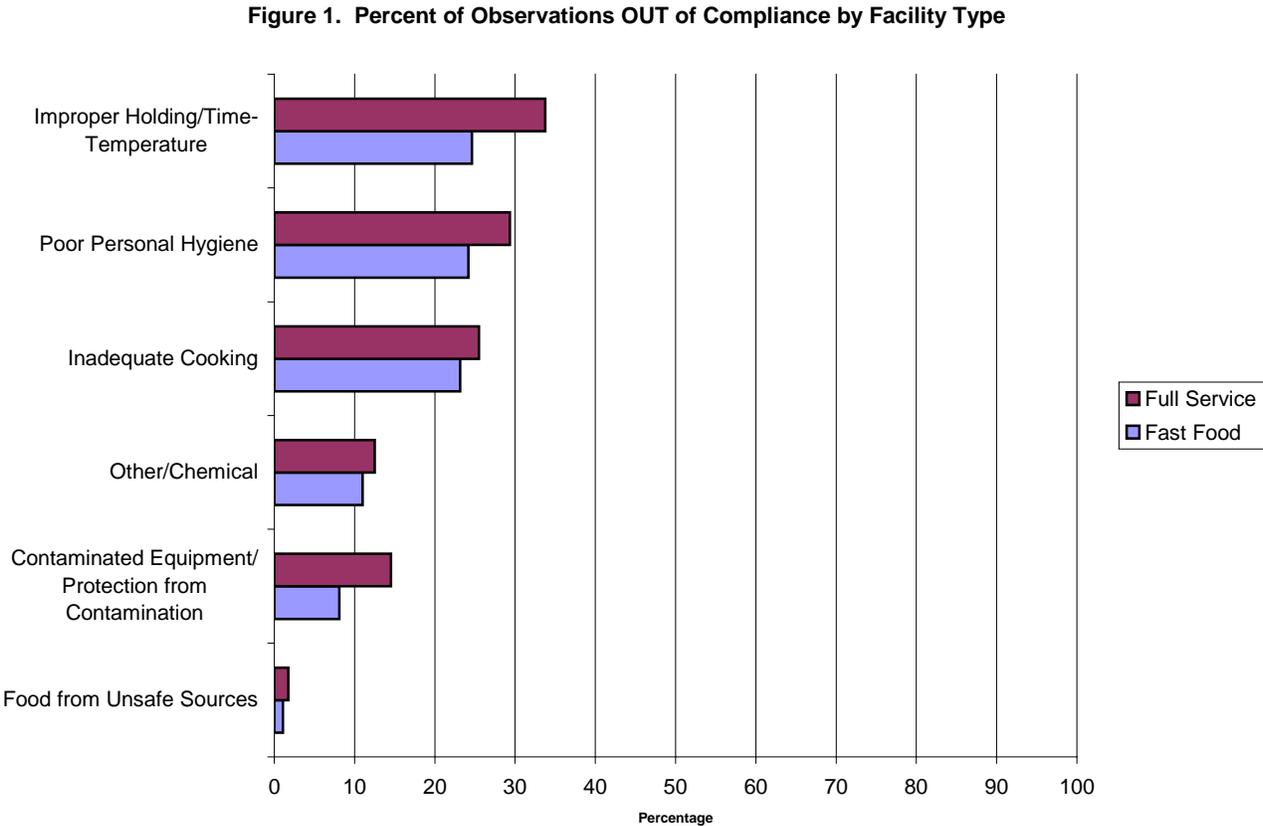
- **Bar charts** (Figures 2, 5, 8) showing the percent of each risk factor's individual data items observed as OUT OF COMPLIANCE; (Figure 1) showing the overall % summary of the most significant out of compliance observations for all facility types combined; and
- **Pie charts** (Figures 3, 4, 6, 7, 9, 10) showing the breakdown of the percent of a facility type's total OUT OF COMPLIANCE observations that can be attributed to each specific individual data.

Only data items with 14 (fast) or 20 (full) or more OUT OF COMPLIANCE observations are individually displayed. Those data items with fewer OUT OF COMPLIANCE observations were also compiled and make up the "REMAINING DATA ITEMS" category in the figures.

IMPROPER HOLDING/TIME AND TEMPERATURE

Proper temperature control is a fundamental element of food safety. Figure 1 reflects the total percent of observations OUT OF COMPLIANCE with Food Code time and temperature requirements designed to limit the growth of organisms of public health concern.

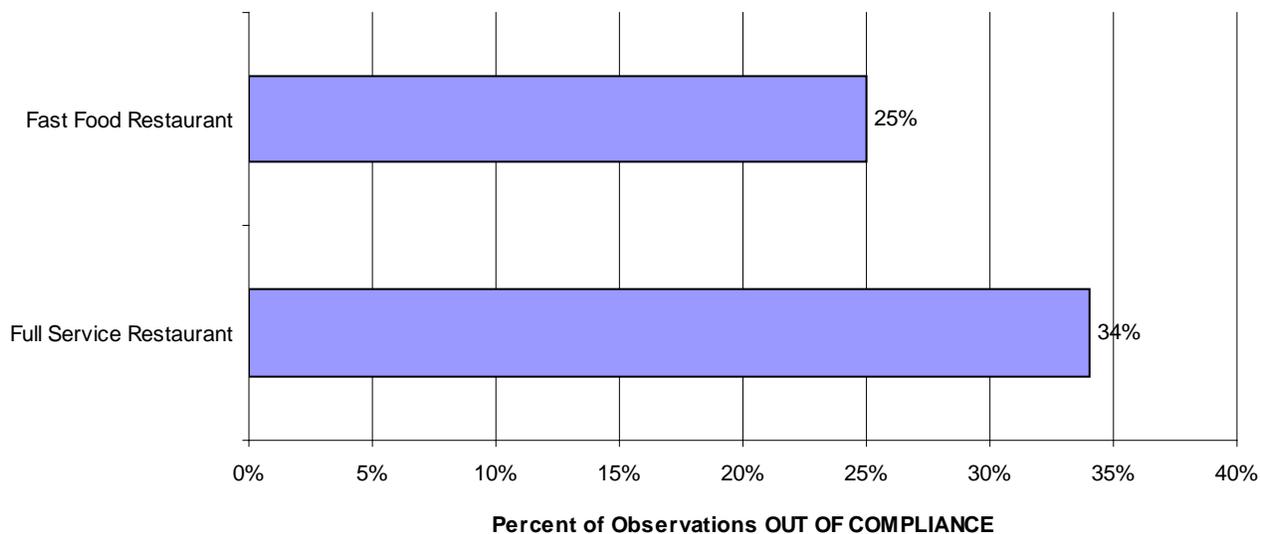
Figure 1. Percent of Observations OUT OF COMPLIANCE, by Facility Type



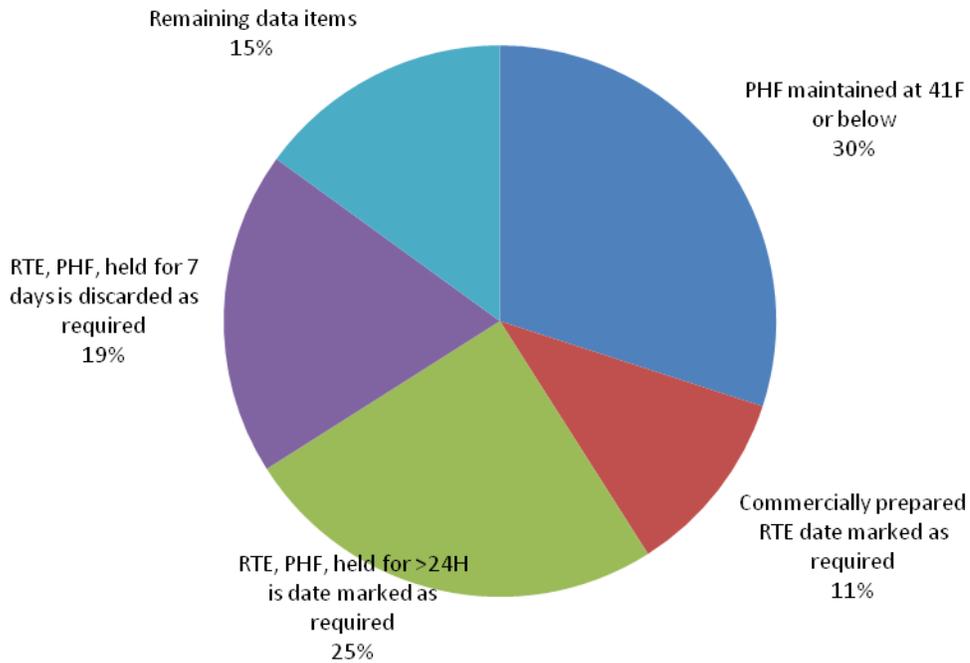
Figures 2, 3 and 4 reflect the relationship (expressed as percentage) of OUT OF COMPLIANCE observations for the individual data items pertaining to the improper holding/time and temperature risk factor. Cold holding, proper cooling, hot holding, date marking, and time as a public health control are some of the data items included in this risk factor.

Cold holding at 41F (5C) was the most frequent temperature violation in both facility types, and was responsible for between 26% and 27% of the OUT OF COMPLIANCE observations. Ready-to-eat food date marking within 24 hours as well as commercial product date marking, were common OUT OF COMPLIANCE observations in both facility types as well. These date marking values are not surprising, since a generous phase-in period was given to operators to implement date marking after the Oregon Food Code was adopted in 2001.

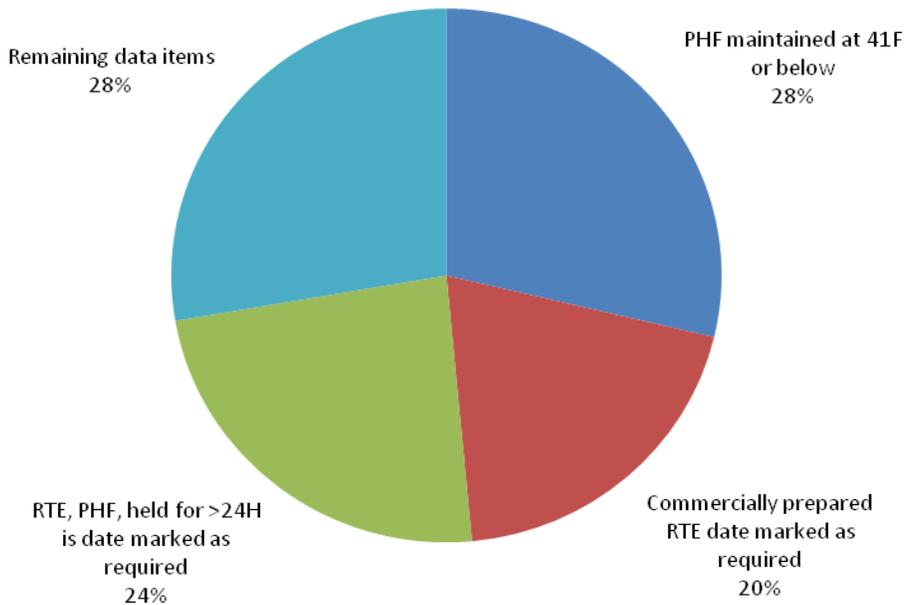
Figure 2. Improper Holding Time and Temperature



**Figure 3. Improper Hold/Time and Temperature
Breakdown of the OUT OF COMPLIANCE Observations by Data Item
Full Service Restaurants**



**Figure 4. Improper Hold/Time and Temperature
Breakdown of the OUT OF COMPLIANCE Observations by Data Item
Fast Food Restaurant**



POOR PERSONAL HYGIENE

Every year between 1988 through 1992, CDC reported that poor personal hygiene of food workers was the second most commonly reported practice that contributed to foodborne disease outbreaks.

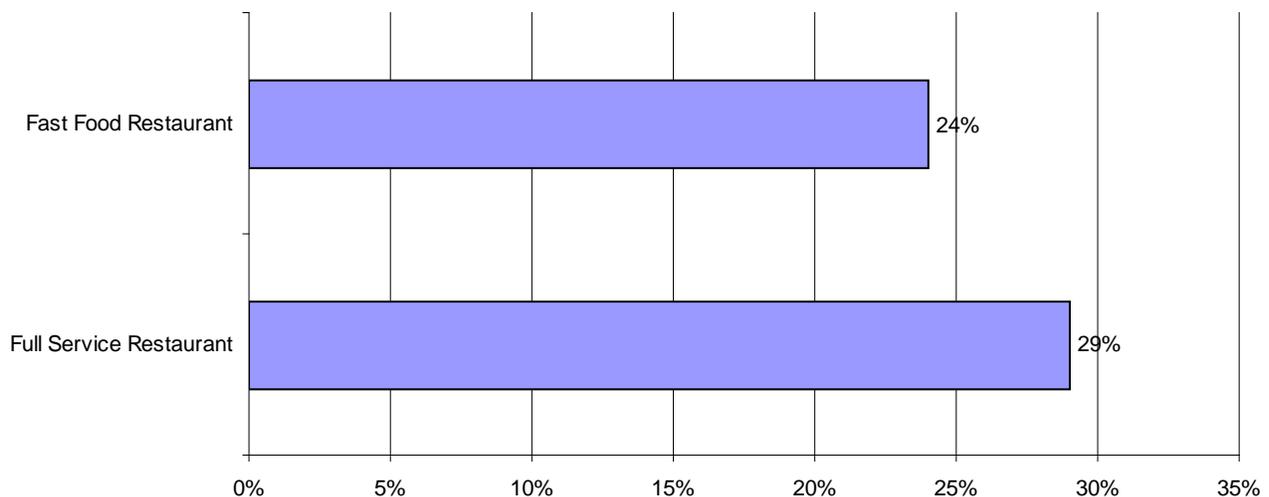
Infected employees are the source of contamination in approximately 1 in 5 foodborne disease outbreaks reported in the United States with a bacterial cause. Most of these outbreaks involve enteric bacteria, i.e. fecal-oral agents spread as a result of poor personal hygiene practices by employees.

Transmission of enteric virus is also of concern. CDC now estimates that Noroviruses are the leading cause of foodborne illness in the United States and reports that hands are the most important means by which enteric viruses are transmitted.

Figure 5 reflects the total percent of observations OUT OF COMPLIANCE with the 1997 Food Code personal hygiene requirements.

Figure 5. Percent of Observations OUT OF COMPLIANCE, by Facility Type

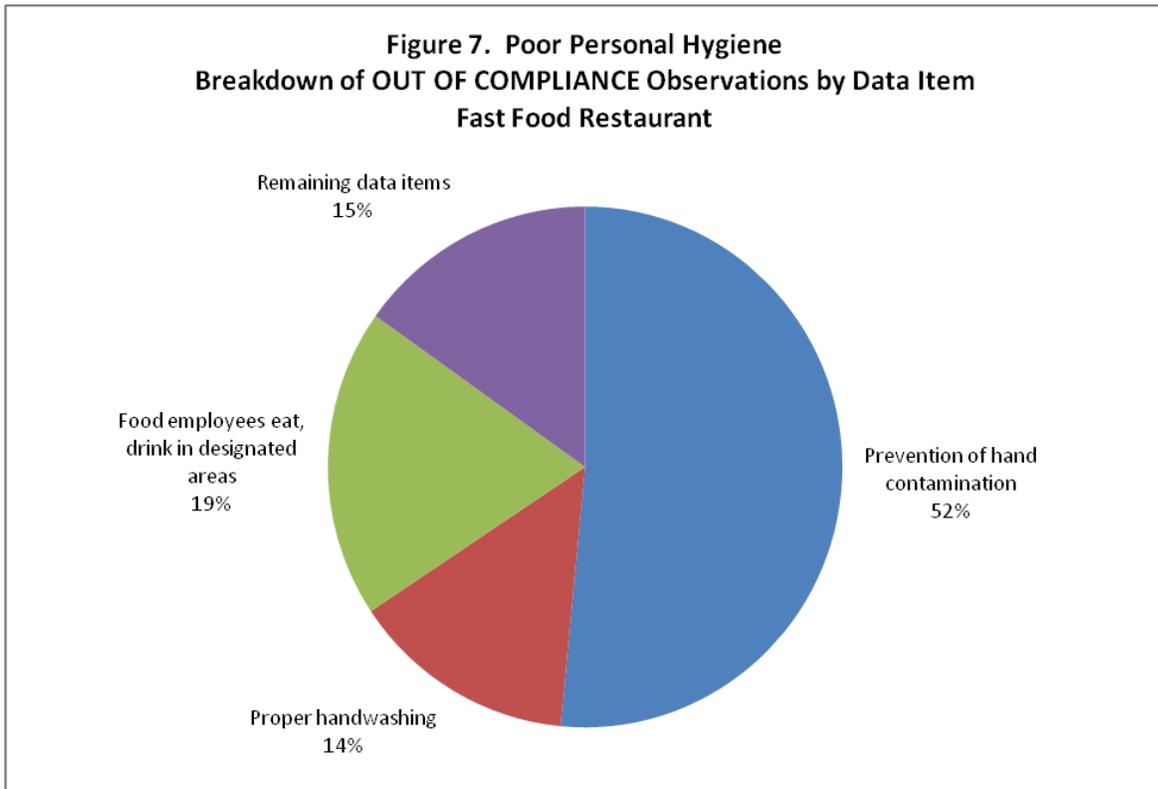
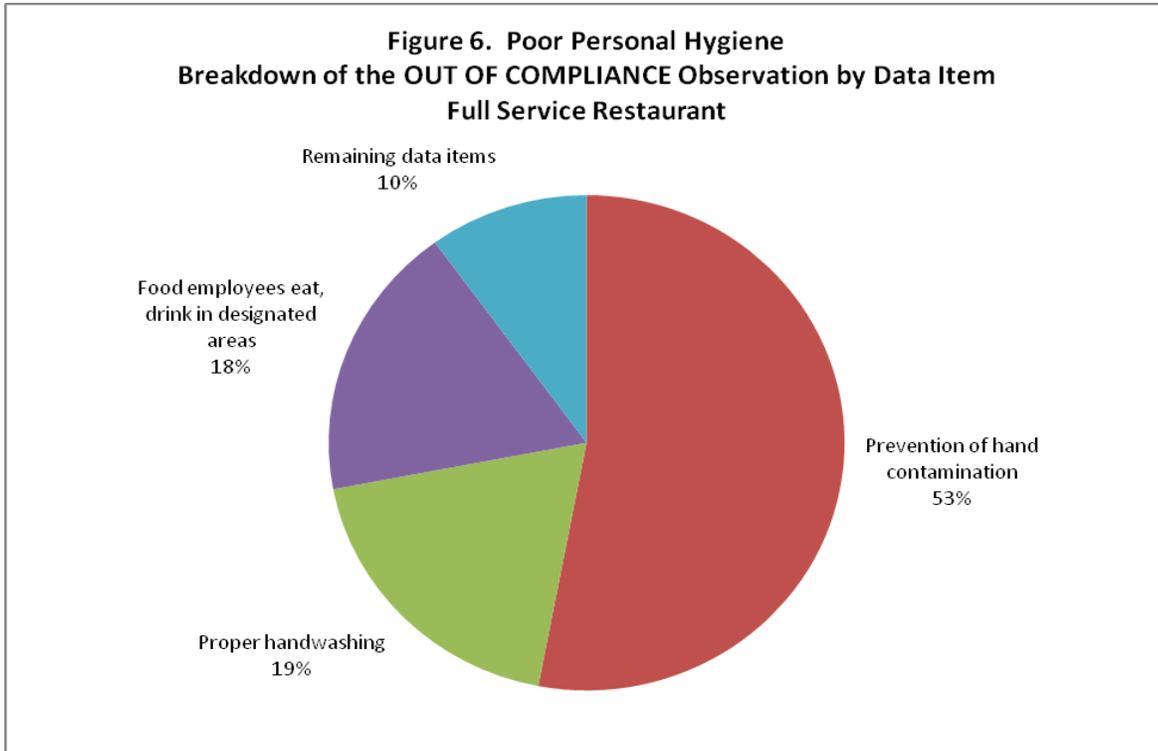
Figure 5. Poor Personal Hygiene Percent of Observations OUT OF COMPLIANCE by Facility Type



Proper and adequate handwashing is critical in controlling the transmission of pathogenic organisms from employees to food. Proper handwashing, prevention of contamination from hands, good hygienic practices, and adequate/accessible facilities are included as individual data items for this risk factor.

Figures 6 and 7 indicate that lack of handwashing was a persistent OUT OF COMPLIANCE observation in both facility types, accounting for 28% of the total personal hygiene OUT OF COMPLIANCE observations. Bare hand contact with ready-to-eat food was the highest OUT OF COMPLIANCE observation because it is not prohibited in Oregon at this time. Inadequate handwashing facilities being conveniently located as well as stocked with paper towels and soap represented 22% of the Poor Personal Hygiene OUT OF COMPLIANCE observations for full service restaurants and 18% for the fast food restaurants. Practices such as eating, drinking, sneezing,

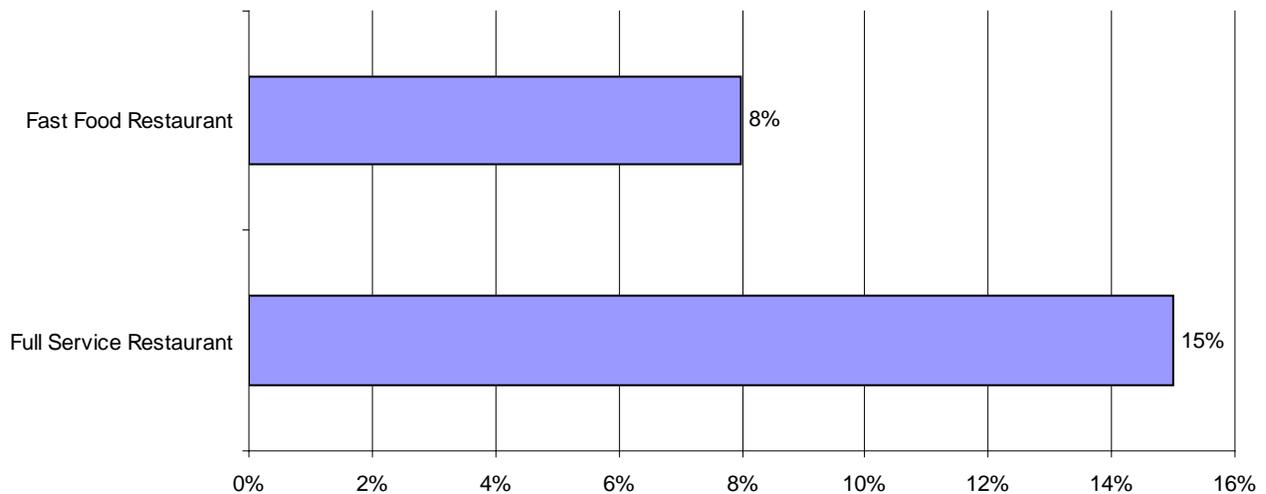
coughing, and the use of tobacco in the food service area were problems in both restaurant types.



CONTAMINATED EQUIPMENT/PROTECTION FROM CONTAMINATION

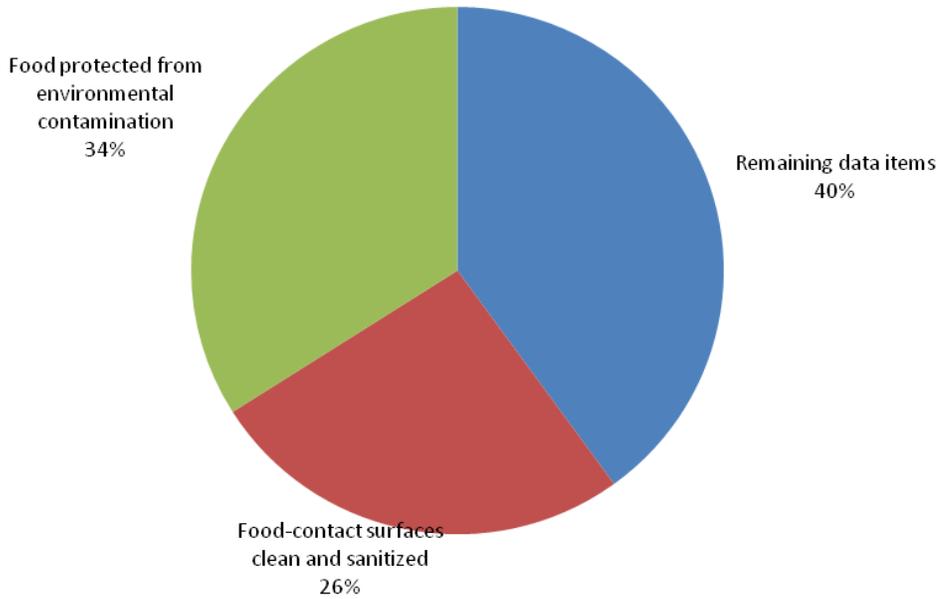
Pathogens can be transferred to food from utensils, equipment, and work surfaces that have not been properly cleaned and sanitized. Cross contamination can also occur when ready-to-eat foods come in contact with raw animal foods or surfaces having contact with raw animal foods. Food may also be contaminated as a result of environmental agents such as dust, condensate, and faulty packaging. Figure 8 reflects the total percentage of observations OUT OF COMPLIANCE with Food Code requirements designed to prevent the contamination of food and food-contact surfaces.

Figure 8. Contaminated Equipment/Protection from Contamination Percent of Observations OUT OF COMPLIANCE by Facility Type

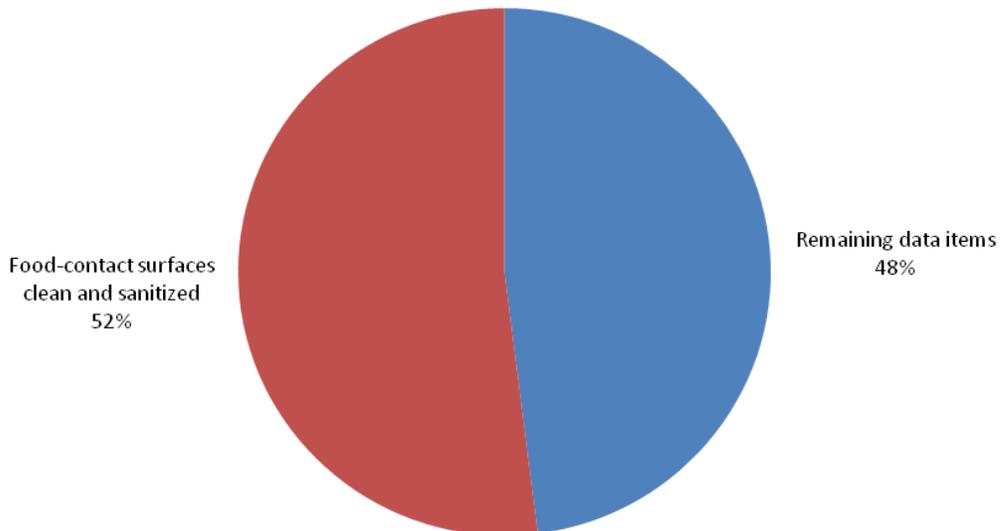


Figures 9 and 10 present the individual data items pertaining to the contamination of food and/or food-contact surfaces for each facility type. Failure to clean and sanitize food-contact surfaces to prevent the contamination of food was a persistent OUT OF COMPLIANCE observation in both establishment types. Cleaning and sanitizing accounted for 27% of the OUT OF COMPLIANCE observations. Separation of raw animal foods and ready-to-eat foods was a significant OUT OF COMPLIANCE observation as well.

**Figure 9. Contaminated Equipment/Protection from Contamination
Breakdown of the OUT OF COMPLIANCE Observations by Data Item
Full Service Restaurant**



**Figure 10. Contaminated Equipment/Protection from Contamination
Breakdown of the OUT OF COMPLIANCE Observations by Data Item
Fast Food Restaurant (Not an item of concern >80% IN)**



INADEQUATE COOKING

The Food Code provides specific time and temperature cooking requirements for various products prepared in retail establishments. These cooking requirements are based on a particular pathogen's resistance to heat and its anticipated load associated with a particular food. In general, inadequate cooking was not a frequent OUT OF COMPLIANCE observation. When cooking *could* be observed, less than 11% of the observations were OUT OF COMPLIANCE. However, in approximately 40% of the assessments conducted, the Specialist did not observe the cooking step. A discussion of the data analysis limitations resulting from data items NOT OBSERVED is found in Field and Statistical Limitations, Section V.

FOOD SOURCE

When a foodborne illness associated with consumption of raw shellfish occurs, it is important to be able to determine the source of these shellfish. Harvesters, dealers, and processors are required to affix identity tags to each container of shellfish. The tag affixed to the shellfish containers identifies whether the harvester and dealer are on the NSSP list and provides specific information, such as harvest location and date of harvest, needed for a traceback investigation. Retention of shellfish tags for 90 days is required if shellstock or raw shellfish is sold or served.

Similarly, facility operators are required to keep written documentation of parasite destruction if they are serving raw fish other than the species allowed under 3-402.11 and 12. No food source items were significant sources of OUT OF COMPLIANCE observations.

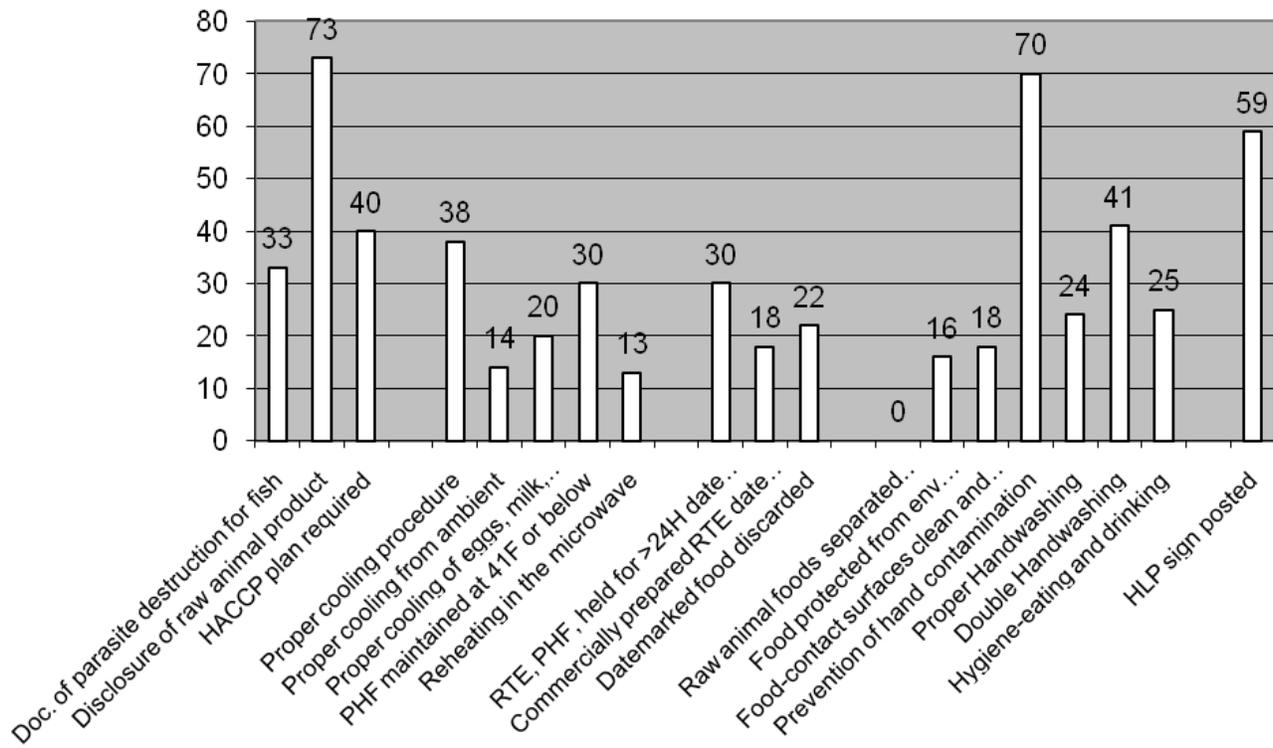
OTHER/CHEMICAL

Contamination of food from chemical and toxic substances can cause serious illness or death. The individual data items related to this category include proper labeling of food containers, maintaining proper separation of food and toxic substances during storage, and using the products according to the specific label instructions found on the containers. These items were not associated with OUT OF COMPLIANCE observations during the study.

E. SUMMARY OF THE MOST SIGNIFICANT OUT OF COMPLIANCE DATA ITEMS

Figure 11 is presented to focus attention on those individual data items that indicate a serious loss of industry management control over behaviors and practices attributed to the occurrence of foodborne illness. This figure summarizes the overall percent (%) of OUT OF COMPLIANCE observations for the most significant individual data items, for both facility types combined.

Figure 11. Overall % Summary of Most Significant OUT OF COMPLIANCE Individual Data Items



Three individual data items exceeded a 40% OUT OF COMPLIANCE observation rate:

- Prevention of Hand Contamination
- Double handwash when required (supplemental item)
- Handwashing Legends sign posted at kitchen handsink (supplemental item)

There were six individual data items that indicate a high OUT OF COMPLIANCE trend but represent very few facilities total:

- Rapid reheating in the microwave (3)
- Proper cooling (5)
- Proper cooling from ambient (1)
- Proper cooling of eggs, milk, shellfish (1)

- HACCP plan when required (2)
- Parasite destruction for fish (1)

The numbers of OUT OF COMPLIANCE OBSERVATIONS are noted in parentheses next to each bulleted item. For example, “Documentation of parasite destruction” was observed to have a 50% OUT OF COMPLIANCE rate, however it was only observed six times during assessments. Because of the small number of total observations, these numbers are not reliable indicators, but are of interest.

If the safety of food in the retail segment of the food industry is to be significantly improved, the managers of retail food establishments must establish effective management control over these individual data items. The retail food industry and the regulatory community must remain focused in their efforts to reduce the individual data items having the most significant OUT OF COMPLIANCE observation rate.

More extensive guidance for regulatory and industry food program managers regarding specific actions to address these significant individual data items is provided in Recommendations, Section VI.

V. FIELD AND STATISTICAL LIMITATIONS

As with all field studies involving data analysis, some internal and external factors influenced the design and scope of the project. Sample size, industry diversity, and available resources are a few of the factors limiting the design of the project.

These factors can be placed in two broad categories:

- A. Field Operational Limitations and
- B. Statistical Limitations

A. Field Operational Limitations

OHA staff collecting the data encountered challenges similar to those encountered by local inspectors conducting routine assessments. Establishment type, the season of the year, the time of day the assessment was conducted, and the length of time available for each assessment are some of the factors that impacted the data collection.

The time of day the assessment was conducted and the length of the assessment are significant factors limiting an inspector’s observations. Often the most desirable time of day to conduct assessments is early in the morning when most of the daily preparation occurs. Assessments conducted in the afternoon hours, therefore, may not be conducive to observing and documenting critical preparation steps. In addition, the length of the assessment plays a significant role in what data can be collected. For example, as much as 6 hours may be required on site to document compliance with the Food Code critical limits for rapid cooling. Due to these field limitations, some individual data items have a high NOT OBSERVED percentage.

Some examples of individual data items that were difficult to observe included:

- Food received at proper temperature;
- Cooking of beef roasts to 130F (54C) for 121 minutes;
- Cooked PHF cooled from 140F (60C) to 70F (21C) within 2 hours and from 70F (21C) to 41F (5C) within 4 hours;
- PHF (from ambient ingredients) cooled to 41F (5C) or below in 4 hours; and
- Foods received at a temperature according to law cooled to 41F (5C) within 4 hours.

These data items require a significant period of time to assess compliance with regard to time/temperature standards or involve processes or operational steps that occur outside traditional regulatory work hours. However, these high NOT OBSERVED percentages may warrant closer assessment for future studies.

B. Statistical Limitations

- Representation of the Population of Each Facility Type

The establishments in each county were placed in alphabetical order and sequentially numbered. OHA staff then used a table of random numbers, generated in Microsoft Excel, to select the particular establishment to inspect. The randomness gives the same chance of selecting establishments having varying degrees of compliance, thus preventing selection bias.

- Precision of Percentages for Each Facility Type

Attempts were made to observe the same 42 risk-related individual data items discussed under Methodology, Section III, E, at each establishment. Many times, some items could not be observed during assessments. If all items were applicable and observable at the time of the assessment, each facility type would have produced about 3650 compliance observations. "Compliance Observations" are observations that could be judged IN COMPLIANCE or OUT OF COMPLIANCE.

The precision of the percentages calculated from the data is directly related to the number of observations included in the analyses. Therefore, the more observations recorded the greater precision of the resulting percentages. For example, the percentage relating to overall IN COMPLIANCE observations as they appear in Table 1, Data Reports and Discussion, Part A, is more precise than the percentage relating to IN COMPLIANCE observations for any individual data item in Tables 3 and 4, Data Reports and Discussion, Part C.

An overall IN COMPLIANCE percentage for all risk factors combined will have 95 percent confidence limits of plus-or-minus 2 percentage points, for the restaurants.

Given the diversity within retail operations, it was anticipated that many individual data items would have relatively small numbers of observations. The project design, therefore, placed more emphasis on the collection of items into the 5 major risk factor categories identified in the Background, Section I. This is more statistically reliable because when grouping the data items into the risk factors, a larger pool of observations is attained.

Types of Comparison Not Supported by the Statistical Design

This project is designed to establish a statewide baseline on the occurrence of foodborne disease risk factors within the retail segment of the food industry, as well as contributing to the nationwide FDA database.

In addition, the project is not designed to support comparisons of chains of fast food restaurants or full service facilities. 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.

VII. RECOMMENDATIONS

- Use to promote consistency statewide
- Use to develop work plan and maintain focus on public health and determine future activities
- Need to develop interventions based on feedback from State Food Service Advisory Committee
- Compare data to annual statistics report for patterns and trends

VII. AREAS FOR FUTURE STUDY

The intent of establishing a national baseline of current compliance with Food Code provisions that address the CDC-identified risk factors is to track the change in the occurrence of risk factors through future comparison studies.

Comparison projects might involve concentrating on specific observations from the initial baseline collection where data were either insufficient or on observations that had a high incidence of not being observed. Such observations might include cooling, cooking, and/or receiving temperatures. Changes in various aspects of the initial project methodology, such as the time and duration of assessments, might facilitate better data collection in these areas.

APPENDIX A

BASELINE DATA COLLECTION REFERENCE SHEET 1997 Food Code

CDC Risk Factor: FOODS FROM UNSAFE SOURCES

Food Source

1. Approved Source

- 1.A. 3-201.11* Compliance with Food Law
3-201.12* Food in a Hermetically Sealed Container
3-201.13* Fluid Milk and Milk Products
- 1.B. 3-201.14* Fish
3-201.15* Molluscan Shellfish
3-202.18* Shellstock Identification
- 1.C. 3-201.16* Wild Mushrooms
3-201.17* Game Animals
- 1.D. *3-603.11 Disclosure of Raw Animal Foods
(1999 Food Code)*

2. Receiving/Condition

- 2.A. 3-202.11* Temperature
3-202.15* Package Integrity
3-101.11* Safe, Unadulterated, and Honestly Presented

3. Records

- 3.A. 3-202.18* Shellstock Identification
3-203.12* Shellstock, Maintaining Identification
- 3.B. 3-402.11* Parasite Destruction
3-402.12* Records, Creation and Retention
- 3.C. 3-502.12* Reduced Oxygen Packaging, Criteria

Pathogen Destruction

4. Proper Cooking Temp

- 4.A. 3-401.11(A)(1)(a)* Raw Animal Foods
- 4.B. 3-401.11(2)* Raw Animal Foods
- 4.C 3-401.11(B)(1)(2) Raw Animal Foods
- 4.D. 3-401.11(A)(3)* Raw Animal Foods
- 4.E. 3-401.11(A)(3)* Raw Animal Foods
- 4.F. 3-401.12* Microwave Cooking
- 4.G. 3-401.11(A)(2)* Raw Animal Foods
- 4.H. 3-401.11(A)(1)(b)* Raw Animal Foods

5. Rapid Reheating for Hot Holding

- 5.A. 3-403.11(A)* Reheating for Hot Holding
- 5.B. 3-403.11(B)* Reheating for Hot Holding - Microwave
- 5.C. 3-403.11(C)* Reheating for Hot Holding -
Commercially processed RTE food
- 5.D. 3-403.11(E)* Reheating for Hot Holding - Remaining
unsliced portions of roasts of beef

CDC Risk Factor: IMPROPER HOLD

Limitation of Growth of Organisms of Public Health Concern

6. Proper Cooling Procedure

- 6.A&B. 3-501.14(A)* Cooling - Cooked PHF
- 6.C&D. 3-501.14(B)* Cooling - PHF prepared from ingredients
at ambient temperature
- 6.E&F. 3-501.14(C)* Cooling - PHF receipt of foods allowed
at 41F during shipment

7. Cold Hold (41F or 45F in existing equipment)

- 7.A&B. 3-501.16(B)*, PHF, Hot and Cold Holding
PHF shall be maintained at 45F or between 41F and 45F in existing equipment not capable of maintaining 41F and the equipment is upgraded or replaced with 5 years of the R.A.'s adoption of the Food Code

8. Hot Hold (140F)

- 8.A. 3-501.16(A)* PHF, Hot and Cold Holding
8.C. 3-501.16(A)* PHF, Hot and Cold Holding

9. Time

- 9.A. 3-501.17(A)(1)(2)* Ready-to-Eat, PHF, Date Marking - On-premises preparation
Food is to be date marked at the time of preparation, with the "consume by" date. This "consume by" date should include the day of preparation and is: (1) 7 calendar days at 5C (41F) or less; or (2) 4 calendar days at 7C (45F)
- 9.B. 3-501.18* Ready-to-Eat, PHF, Disposition
Food shall be discarded if not consumed within 7 calendar d days at 5C (41F) or less; or 4 calendar days at 7C (45F)
- 9.C. 3-501.17(C)*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 consumer by date which is, including the day the original container is opened:
1. 7 calendar days at 5C (41F) or less; or
 2. 4 calendar days at 7C (45F)
- 9.D. 3-501.19* Time as a Public Health Control

CDC Risk Factor: CONTAMINATED EQUIPMENT

Protection from Contamination

10. Separation/Segregation/Protection

- 10.A. 3-302.11(A)(1)* Packaged and Unpackaged Food - Separation, Packaging, and Segregation
Separate raw animal foods from raw RTE and cooked RTE foods

For marking the status of 10.A.:

N.A. (Not Applicable) = If establishment has vegetarian menu only.

CDC Risk Factor: CONTAMINATED EQUIPMENT

Protection from Contamination

10. Separation/Segregation/Protection

- 10.B. 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 prevent cross contamination of one type with another, or by preparing different types of food at different times or in separate areas.
- 10.C. 3-302.11(A)(4-6)* Packaged and Unpackaged Food - Separation, Packaging, and Segregation

3-304.11(B)* Food Contact with Equipment and Utensils
- 10.D. 3-306.14(A)(B)* Returned Food, Reservice or Sale

11. Food Contact Surfaces

- 11.A. 4-601.11* Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils

4-701.10* Sanitization of Equipment and Utensils - Food-Contact Surfaces and Utensils

4-701.11* Sanitization of Equipment and Utensils - Before Use after Cleaning - Frequency

CDC Risk Factor: POOR PERSONAL HYGIENE

Personnel

12. Proper, Adequate Handwashing

- 12.A. 2-301.11* Clean Condition
- 2-301.12* Cleaning Procedure
- 2-301.14* When to Wash
- 2-301.12* Where to Wash

13. Good Hygienic Practices

- 13.A. 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
- 13.B. 2-301.13* *Double Handwash as Required*
 (Oregon Food Code)

14. Prevention of Contamination from Hands

- 14.A. 3-301.11* Preventing Contamination from Hands

15. Handwash Facilities

- 15.A. 5-203.11* Handwashing Lavatory - Numbers and Capacities
- 5-204.11* Handwashing Lavatory - Location and Placement
- 5-205.11* Using a Handwashing Lavatory - Operation and Maintenance
- 15.B. 6-301.11 Handwashing Cleanser, Availability
- 6-301.12 Hand Drying Provision

CDC Risk Factor: OTHER

Foreign Substances

16. Chemical

- 16.A. 3-202.12* Additives
 3-302.14* Protection from Unapproved Additives

NOTE: Re: 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.

For marking the status of 16.A.:

IN compliance = No unapproved additives on site; IF have sulfites on premises, they are used properly.

OUT of compliance = Unapproved additives found on premises and improperly used, e.g., on fresh fruits and vegetables.

N.O. (Not Observed) = Not an option for response on this item.

N.A. (Not Applicable) = Food establishment does not use any additives or sulfites.

- 16.B. 7-101.11* Identifying Information, Prominence -
 Original Containers
 7-102.11* Common Name - Working Containers

Operational Supplies and Applications

- 7-201.11* Separation - Storage
7-202.11* Restriction - Presence and use
7-202.12* Conditions of Use
7-203.11* Poisonous or Toxic Material Containers -
Prohibitions
7-204.11* Sanitizers, Criteria-Chemicals
7-204.12* Chemicals for Washing Fruits and
Vegetables
7-204.13* Boiler Water Additives, Criteria

BASELINE DATA COLLECTION FORM

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

Baseline Data Collection Form

Date: _____ Inspector: _____

Establishment: _____

Address: _____

Manager: _____

Facility Type: Quick service Full service

Additional Notes:

IN= item found in compliance
NO= not observed

OUT=item found out of compliance
NA= not applicable

FOOD SOURCE

STATUS 1. Approved Source

- _____ A. All food from Regulated Food Processing Plants/ No home canned foods
- _____ B. All shellfish from NSSP listed sources. No rec caught shellfish received or sold
- _____ C. Game, wild mushrooms harvested with approval of Regulatory Authority
- _____ D. *Disclosure for raw or undercooked foods - Caesar dressing, seared tuna, cevechi, sushi, steak tartar*

STATUS 2. Receiving/ Condition

- _____ A. Food received at proper temps/ protected from contamination during transport and receiving/ food is safe, unadulterated

STATUS 3. Records

- _____ A. Shellstock tags/labels retained for 90 days from the date container is emptied
- _____ B. As required, written documentation of parasite destruction maintained for fish products
- _____ C. CCP monitoring records maintained in accordance with HACCP plan when required

PATHOGEN DESTRUCTION

STATUS 4. Proper Cooking Temp for PHF

- _____ A. Raw eggs broken for immed service cooked to 145F for 15 sec, eggs not prepared for immed service cooked to 155F for 15 sec
- _____ B. Comminuted fish, meats, game animals 155F for 15 sec
- _____ C. Beef roasts to 130F for 121 min or as chart specifies
- _____ D. Poultry, stuffed fish, meat pasta, stuffed ratites, or stuffing with these to 165F for 15 sec
- _____ E. Wild game animals to 165F for 15 sec
- _____ F. Raw animal foods cooked in microwave are stirred and heated to 165F and allowed to stand covered 2 min after heating
- _____ G. Pork, ratites, injected meats are cooked to 155F for 15 sec
- _____ H. All other PHF cooked to 145F for 15 sec

STATUS 5. Rapid Reheating for Hot Holding

- _____ A. PHF reheated to 165F for 15 sec
- _____ B. Microwaved foods are heated to 165F or higher
- _____ C. Commercially processed RTE food, if reheated, held at 140F or above
- _____ D. Remaining unsliced portions of beef roasts are reheated for hot holding according to chart

LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

STATUS 6. Proper Cooling Procedure (**Note temps above 41F on blank lines**)

- _____ A. Cooked PHF is cooled from 140F to 70F w/in 2 hours and from 70F to 41F w/in 4 hours
- _____ B. PHF (from ambient ingredients) is cooled to 41F or below within 4 hours
- _____ C. Foods received at a temperature according to law are cooled to 41F within 4 hours

STATUS 7. Cold Hold

- _____ A. PHF is maintained at 41F or below

STATUS 8. Hot Hold

- _____ A. PHF is maintained at 140F or above
_____ B. Roasts are held at a temp of 130F or above

STATUS 9. Time

- _____ A. RTE, PHF, held for >24 hours is date marked as required
_____ B. RTE, PHF, held at 45F for 4 days or 41F for 7 days is discarded as required
_____ C. Commercially prepared RTE, PHF is date marked as required
_____ D. When time is the only public health control, food is cooked and served w/in 4 hours

PROTECTION FROM CONTAMINATION

STATUS 10. Separation/ Segregation/ Protection

- _____ A. Food is protected from cross contamination by separating raw animal foods from raw RTE food /cooked RTE food
_____ B. Raw animal food are separated from each other during storage, prep, holding and display
_____ C. Food is protected from environmental contamination
_____ D. After being served or sold to a consumer, food is not re-served

STATUS 11. Food Contact Surfaces

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

STATUS 12. Proper, Adequate Handwashing

- _____ A. Hands are clean and properly washed when and as required

STATUS 13. Good Hygienic Practices

- _____ 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. FH experiencing sneezing, coughing or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service articles
_____ B. *Employees wash their hands twice after contacting bodily fluids or discharges, toileting, before beginning or returning to work*

STATUS 14. Prevention of Contamination From Hands

- _____ A. Employees do not contact exposed, RTE with bare hands

STATUS 15. Handwash Facilities

- _____ A. Conveniently located and accessible for employees
_____ B. Supplied with soap/ paper towels/ hand dryers/warm water

FOREIGN SUBSTANCES

STATUS 16. Chemical

- _____ A. No unapproved food or color additives. Sulfites are not applied to fresh fruits and vegetables for raw consumption
_____ B. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, personal items are identified, stored and used properly
_____ C. Poisonous or toxic materials held for retail sale are properly stored