DEVELOPING A BASELINE ON THE OCCURRENCE OF FOODBORNE ILLNESS RISK FACTORS

DATA COLLECTION INSTRUCTION MANUAL

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Annexes

Chapter 1 – Introduction

PURPOSE AND SCOPE

Many state and local government officials have expressed a desire to conduct baseline measurements of the occurrence of foodborne disease risk factors. Such measurements can be made with respect to the Food and Drug Administration's (FDA) *Food Code* and with respect to your own local codes. Essential background information is in the *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, published by the FDA in August of 2000. This Report can be accessed and downloaded from FDA's web site: http://vm.cfsan.fda.gov/~dms/retrsk.html.

FDA has prepared this instruction manual to assist you in conducting local baselines. You can get the best personal guidance on the methodology from FDA's Regional Retail Food Specialists. Annex VIII contains contact information for the FDA Regional Food Specialist assigned to your geographic area.

The most important determinant of the quality of your baseline measurements will be expertise in:

- Observing and documenting food safety procedures and practices; and
- Developing methodologies to ensure statistically valid compilations and evaluation of the data collected.

While many jurisdictions possess the technical knowledge and skills to observe and assess food safety practices to ensure adherence to a specific standard, few possess the statistical expertise to develop a sound methodology to ensure a valid and meaningful baseline. FDA has developed this manual as a tool for jurisdictions to assess critical considerations in the design of their baseline.

The design of FDA's baseline and the guidance presented in this manual has been primarily developed by the Center for Food Safety and Applied Nutrition's (CFSAN) Division of Mathematics. Subject matter experts were consulted to ensure statistical validity of conclusions derived from the analysis of the data.

Regulatory agencies may wish to customize their baselines to address specific needs or concerns within their jurisdictions. FDA recognizes that there are many ways to design and conduct a statistically sound baseline project. Jurisdictions planning to deviate from the FDA approach or the instructions contained in this manual are strongly encouraged to obtain consultation from technical experts familiar with this type of statistical model and assessment.

Chapter 2 – Baseline Planning Considerations

KEY CONCEPTS PRESENTED IN THIS CHAPTER

- Determine your purpose and objectives for conducting the baseline;
- Determine whether comparing your results to those contained in the FDA baseline or other jurisdictions will be important to your agency;
- Assess availability of resources and technical expertise to develop and implement the project; and
- Evaluate data analysis capabilities

PURPOSE AND OBJECTIVES FOR DEVELOPING THE BASELINE

FDA's data collection produced a baseline of occurrences of foodborne illness (FBI) risk factors so that overall national upward and downward trends over time could be measured. FDA did not produce regional, state, or local baselines, nor did it take into account differing local regulations. Therefore, FDA has no information on state and local conditions as such.

State and local regulatory jurisdictions have an opportunity to establish baselines specific to their oversight responsibilities. By establishing jurisdictional baselines, regulatory agencies can assess the effectiveness of intervention strategies, such as training programs, consultation visits or risk control plans, in reducing foodborne illness risk factors.

Establishing a retail food program baseline on the occurrence of foodborne illness risk factors:

- Provides a quantifiable measurement of FBI risk factors within the foodservice and retail food segment of the industry;
- Establishes a mechanism to track trends over time related to the occurrence of FBI risk factors, and
- Assesses the effectiveness of national retail food safety initiatives and their impact on reducing the occurrence of FBI risk factors.

DETERMINE THE IMPORTANCE OF BASELINE COMPARABILITY

The determination of whether comparability is important will be one that a jurisdiction needs to make for itself. From experience, we have learned that decision-makers at all levels want to assess the rate of occurrence of foodborne illness risk factors in their community against a national standard or trend. These types of assessments are critical when decisions are made regarding human and

financial resource allocations. If the initial design of the baseline does not incorporate the basic elements to ensure the ability to compare trends, any such efforts to compare data with other jurisdictions or the national baseline will be meaningless.

If a jurisdiction wants to compare the results of its baseline to FDA's, four basic principles must be incorporated into the design of its study. Each of these will be expanded in Chapter 6 – Baseline Comparability.

1. Preserve the 42 risk-related data items as they are on FDA's data collection form.
2. Do not merge facility types with each other or with new ones.
3. Maintain the marking system for observations and preserve both codes for "not applicable" and "not observed."
4. The addition of new data items to the original 42 is acceptable.

ASSESS AVAILABILITY OF RESOURCES

Jurisdictions will need to assess their resource capabilities for supporting the design and implementation of the baseline. An agency must consider both the food safety expertise of its field staff, as well as the availability of personnel versed in statistical analysis and computer programming before it embarks on developing a customized baseline. Each jurisdiction must assess and balance the benefits of developing a customized baseline approach against the human and financial resource commitment needed to deliver the project.

EVALUATE DATA ANALYSIS CAPABILITIES

FDA developed a computer data analysis software program that generates reports to measure:

- OVERALL PERCENT (%) of OBSERVABLE and APPLICABLE Data Items observed IN COMPLIANCE for each of the 9 Facility Types;
- PERCENT (%) of TOTAL OBSERVATIONS observed IN COMPLIANCE for each of the 9 Facility Types for controlling each of the risk factors; and
- INDIVIDUAL DATA ITEMS with the highest OUT OF COMPLIANCE observations for each of the 9 facility types. These data items have been identified as needing PRIORITY ATTENTION for each of the 9 facility types.

The above summary of FDA reports presented in the previous paragraph is intended to provide an illustration of the types of the reports that have been generated. FDA's computer software program for data analysis and report generation is ACCESS compatible and available at no cost to interested jurisdictions. Jurisdictions interested in this software program should contact their FDA Regional Food Specialist.

There are many ways that a jurisdiction may conduct a meaningful analysis of the data collected. Jurisdictions that choose not to use the FDA methodology or software program should give consideration to the types of reports they will want to generate from the data collected.

Chapter 3 - Determining Sample Size for the Baseline

KEY CONCEPTS PRESENTED IN THIS CHAPTER

- Determine industry segments/facility types;
- Confirm establishment inventory; and
- Determine sample size for the Baseline and for each identified facility type;

DETERMINE INDUSTRY SEGMENTS AND FACILITY TYPES

FDA constructed its baseline using three industry segments comprised of 9 facility types. A direct focus on these industry segments provides a breadth of coverage of general and highly susceptible populations while also covering the vast majority of establishment types.

TABLE 1

Industry Segments and Facility Types

INDUSTRY SEGMENT	FACILITY TYPE
Institutions	Hospitals Nursing Homes Elementary Schools (K – 5)
Restaurants	Fast Food Restaurants Full Service Restaurants
Retail Food Stores	Deli Department Meat Department Seafood Department Produce Department

FDA's national baseline is the compilation of 9 separate baselines, one for each of the nine facility types.

A jurisdiction may not have regulatory oversight responsibility for all of the 9 facility types presented above. Jurisdictions still can develop baselines that are comparable to the FDA Baseline. As few as one facility type can be used to make a baseline measurement that has value and can be compared with FDA's and other regulatory jurisdictions baselines for that same facility type.

The Baseline does not have to be restricted to the nine facility types identified by FDA. A jurisdiction may add different facility types to the baseline, such as Day Care Centers or Secondary (High) Schools. If comparability with the national baseline is important to the jurisdiction, the data from these additional facility types would simply be excluded when comparisons are made to the FDA Baseline.

If a jurisdiction intends to compare its data with the FDA Baseline, then it will be essential that one does not merge any of the existing 9 facility types identified above. For example, comparability will be lost if Fast Food Restaurants and Full Service Restaurants are lumped together into one facility type called Restaurants. The rationale for maintaining the integrity of the 9 facility types is presented in Chapter 6 – Baseline Comparability.

CONFIRM ESTABLISHMENT INVENTORY

One advantage some state and local jurisdictions have in developing a more precise baseline on the occurrence of foodborne illness risk factors is that they have clearly defined establishment inventories. In most cases, establishment inventories are defined by active permits. Jurisdictions need to confirm that all active establishments are included in the inventory. It is from this jurisdictional inventory that individual establishments will be placed into specific facility types and randomly selected as a data collection site for the baseline.

It may be the case that a jurisdiction does not have direct regulatory oversight of food service and/or retail food establishments that will be included as part of their baseline. Examples of this scenario would include:

- States that have delegated direct inspection work to county or local jurisdictions through agreements or contracts; or
- Jurisdictions in which specific facility types may be regulated by different agencies. This often occurs when the State health agency has direct regulatory responsibility for restaurants while the State Department of Agricultural regulates retail food stores.

Jurisdictions may choose to work together on the Baseline to develop a comprehensive establishment inventory. This takes some coordination and cooperation between agencies but often results in a more efficient use of limited resources, particularly travel time associated with data collection at randomly selected facilities located throughout a large region or state.

SELECTION OF FACILITY TYPES

Annex I contains some broad definitions for the 9 facility types that comprise FDA's baseline. It is not necessary to have precise boundaries on the facility

types because fringe establishments within any facility type can still contribute some observations relevant to the category in which they are ultimately placed.

There is no single or best method for placing establishments into designated facility types. Jurisdictions will have to use their staff's years of experience in the field to characterize the few places that may not fit nicely into a specific facility type. Whatever criterion is used to place the fringe establishments into a specific facility type, it is important that the jurisdiction consistently apply it in all cases when such assessments must be made.

ESTABLISHMENT RISK CATEGORIZATION

Another important aspect of establishing a baseline on the occurrence of foodborne illness risk factors is the ability to observe food safety procedures and practices that, if not conducted properly, will have the potential of causing illness or injury. In determining the pool of establishments eligible for random selection, FDA made a concerted effort to eliminate those establishment types that handled only pre-packaged food items or performed food preparation activities that have been historically low risk.

The Risk Categorization of Food Establishments, presented in Annex II, should be used as a general guideline for determining what type of establishments should be included in the sample pool. As a general rule-of-thumb, establishments that meet the criteria in Risk Types 2 – 5 should be included, while those identified as meeting the description of Risk Type 1 should be excluded.

The criterion used to describe the various risk categories is general at best. The Risk Categorization of Establishments table was not meant to provide definitive criteria for the scope of establishments to be included in the baseline. It was meant to serve as an additional tool to assist in the selection process. Establishments should be included in the data collection if their operation includes food preparation procedures that if not controlled properly, could result in the occurrence of one or more of the CDC-identified foodborne illness risk factors.

DETERMINE MINIMUM SAMPLE SIZE FOR THE BASELINE

To assist jurisdictions in determining a statistically valid minimum sample size, Table 2 is provided on the following page. Based on the total number of establishments available, a recommended minimum sample size is provided for each facility type.

For example, if a jurisdiction has 374+ fast food establishments, the minimum sample size for this facility type will be 87. If the same jurisdiction has 6 Hospitals, then all 6 will be included in the baseline

TABLE 2

Minimum Sample Size for Each Facility Type

Inventory Size	Sample Size*
<9	ALL
9	8
10 – 12	9
13	12
14 – 19	14
20 – 24	18
25 – 28	23
29 – 31	24
32 – 36	27
37 – 43	29
44 – 51	33
52 – 58	38
59 – 73	42
74 – 81	44
82 – 96	48
97 – 103	53
104 – 133	57
134 – 148	59
149 – 163	63
164 – 186	68
187 – 261	72
262 – 291	74
292 – 328	78
329 – 373	83
374+	87

***NOTE:** A detailed presentation of the rationale supporting this approach to selecting a statistically valid sample size is presented in Annex III.

A fictitious example of a regulatory jurisdiction is presented below to illustrate the application of the process described above.

TABLE 3

Illustration – Jurisdiction Baseline Minimum Sample Size

FACILITY TYPE	ESTABLISHMENT INVENTORY	MINIMUM SAMPLE SIZE
Hospitals	6	6
Nursing Homes	36	27
Elementary Schools	48	33
Fast Food Restaurants	420	87
Full Service Restaurants	360	83
Meat Markets/Depts.*	180*	68
Seafood Stores/Depts.*	50*	33
Deli Stores/Depts.*	125*	57
Produce Markets/Depts*	150*	63
TOTAL	**1375***	**457**

*** NOTE:** Many retail food stores contain more than one of the facility types, noted with asterisks, in the chart above (meat, seafood, deli, produce). Some random sampling methodologies will provide an opportunity to conduct inspections of each of the facility types present within an establishment (A few of these will be discussed in Chapter 4 – Random Selection of Establishments). This will result in having to visit fewer establishments while still achieving the sample size required for meat, seafood, deli, and produce facility types.

REGIONAL BASELINE OPPORTUNITIES

Many jurisdictions have relatively small establishment inventories. Some are one-person health jurisdictions. Small jurisdictions may consider working together to establish a regional baseline. To accomplish this, they would pool their establishment inventories and follow a random selection process. The sample size and selected establishments would have a regional distribution allowing the jurisdictions to collectively determine specific responsibilities for the actual data collection.

In preparation for the random selection of establishments for the baseline, a jurisdiction must first complete the placement of the establishments in their inventory into the appropriate facility type category. There are several ways to list the establishments for each facility type. This can be done alphabetically, by street address, permit number, etc.

Chapter 4 – Random Selection of Establishments

KEY CONCEPTS PRESENTED IN THIS CHAPTER

- Determine an appropriate random sampling method for the selection of establishments;
- Simple random sampling for jurisdictions with a defined establishment inventory and few travel restrictions;
- Special considerations for the selection of meat, seafood, deli, and produce stores/departments;
- Two-stage random sampling for large jurisdictions that cannot easily obtain a defined establishment inventory or have major travel restrictions.

RANDOM SAMPLING METHODS FOR BASELINE DATA COLLECTION

In most baseline data collections, a state or local agency will be collecting data from only part of its establishment inventory. The agency will know a lot about the history of many establishments, and could pick the best or the worst. The agency will almost never want to do that, however, because it will want the baseline to be representative of the whole inventory. In order to have a good chance to get representative results, the agency will need a statistically sound method of sampling from its inventory.

The following pages provide a simple step-by-step guide for the random selection of establishments that will be included in a baseline data collection project. Two approaches are presented here.

A. Simple Random Sampling
B. Two-Stage Random Sampling

For a more in-depth discussion on these random sampling methodologies refer to Annex IV.

Jurisdictions with the ability to obtain defined establishment inventories are strongly encouraged to use the simple random sampling methodology. If you decide to use the simple random sampling method, it is important to note that there are some special considerations that apply to its use in the selection of establishments for meat, seafood, deli and produce facility types.

Meat, seafood, deli, and produce facility types may appear separately as free-standing establishments. They may also be part of an establishment that has multiple facility types such as a retail food store. Two options are presented in

this Chapter to ensure that facility types in both these scenarios are properly reflected in the data.

SIMPLE RANDOM SAMPLING

Step 1 – Define your establishment inventory by facility type.

A. Verify that all the active food establishments within the jurisdiction are included in the inventory.

B. To the extent feasible, remove any establishments that have been placed in a low-risk category. (For additional guidance refer to the Establishment Risk Category discussion on page 10 and the chart in Annex II).

C. Separate the remaining establishments from the inventory into their appropriate facility type (Reference pages 8 – 10 and Annex I). Each facility type then will have its own separate establishment inventory (Special considerations for restaurants are discussed in Annex IV, Section D; for groceries stores refer to Annex IV, Section E).

For example, the fast food restaurant inventory list may include 260 establishments.

Step 2 – Assign numbers to all establishments within each facility type inventory from one (1) to whatever the total is.

Using our example, all of the establishments within the fast food Facility type will be numbered from 1 to 260.

Step 3 – Determine the minimum number of establishments needed for EACH facility type to have a statistically valid study using Table 2 on page 12.

In Step 1 the establishment inventory for fast food restaurants is 260. Using Table 2, the minimum sample size is 72.

Step 4 – For each facility type, estimate how many substitute establishments will exceed your needs. In most cases, when you attempt the minimum sample number of inspections, you will find one or more establishments in a situation that prevents completion of the inspection (e.g.: out of business; temporarily closed for renovations that might not be completed by the end of your data collection period). In such cases you will need to schedule additional inspections at substitute establishments in order to achieve the minimum sample size.

These substitutes will also be chosen at random, so the most efficient procedure is to choose the minimum sample and a pool of substitutes all at one time, so as not to have to go through random number selection again and again. The only goal here is to pick a big enough pool of substitutes to guarantee that you will have more than you will need. A simple guideline would be to pick twice the number you think will be sufficient.

Using our example, if we think that 20 substitutes should be more than enough, we will guarantee, sufficiency by picking a substitute pool of 40 extra fast food establishments.

Step 5 – For each facility type, decide whether or not to oversample. If travel time is not a major consideration, skip to Step 6. If you are planning travel routes across a wide area, then you should consider an option we call "oversampling" as a way to reduce travel time and expenses.

In most cases, if you only include the minimum sample number of inspections in your initial scheduling of travel, you will find yourself repeating some of the travel in order to inspect any required substitutes. Indeed, you could find yourself, near the end of the project, sending a person to four corners of a state to pick up just four more establishments.

You can prevent or minimize any retracing of your travel routes if you use the initial part of the substitute list to enlarge your sample size beyond the minimum, for initial scheduling purposes. We call this "oversampling" for the purposes of this manual. When you oversample, you must attempt data collection for the entire expanded sample and will usually end up with more data than the minimum. As long as you succeed at collecting at least the minimum sample amount of data, you will not need to schedule any trips to inspect substitute establishments. Any data beyond the minimum amount will also be included in your baseline.

If you oversample by a small margin, you will probably succeed at inspecting at least the minimum number of establishments in your original schedule. Occasionally, you might still need substitutes, but that will occur only rarely, and the cost in travel time across a wide area will be much smaller than if you had not oversampled. The size of the oversample is just an intuitive estimate.

In our example, the baseline covers a large geographic area, so the project planner decides to oversample by 5 fast food establishments, leaving the last 35 of the 40 substitutes for later use if still needed. (Now the number selection to follow will include 72 + 5 = 77 in the oversample plus 35 substitutes.)

Step 6 – From each facility type inventory, randomly select enough establishment numbers to cover the minimum sample size, any oversampling that might have been chosen, and the chosen number of potential substitute establishments. Random numbers may be obtained from published tables, spreadsheet software packages, and some scientific calculators. Individuals directly responsible for the random selection of establishments should also read Annex IV, Section B for detailed help.

From our example, in which oversampling was opted, 112 distinct random numbers from 1 to 260 will be selected. The first 77 will be used for initial scheduling. The last 35 numbers will supply any substitute establishments that might be needed to reach the minimum sample size of 72, being used in the order in which they were selected.

Step 7 – Conduct Baseline data collection at the randomly selected establishments.

In our example, if after attempting inspections in the 77 establishment oversample, at least the minimum 72 inspections are completed, then the data collection for the fast food facility type is finished. If more than 72 are done, include the data from these as well. If less than 72 are done, use substitute establishments in the order that they are selected until 72 inspections are completed.

SPECIAL CONSIDERATIONS (MEAT, DELI, SEAFOOD, AND PRODUCE FACILITY TYPES)

Approach 1 – For jurisdictions that desire to use a combined inventory list for meat, seafood, deli and produce facility types.

A combined inventory list is one that includes both standard retail food stores that may include multiple departments and freestanding delis, seafood stores, butcher shops, produce markets, etc. By using a combined inventory list, jurisdictions can take advantage of the opportunity to visit multiple facility types (meat, seafood, deli and produce) when they are present in one retail food store. This approach could provide some efficiency in the use of resources available for the data collection.

Step 1 – Develop a master list of establishments that are expected to contain one or more of these retail food store facility types. (The master establishment list should include free-standing establishments that may have only one facility type as well as establishments with multiple facility types.) If such a list is not available, several approaches may be used to develop one.

- Use existing permits and food program databases to identify facility types in each establishment.

- During routine inspections, confirm the facility types present in each of the establishments inspected. (This includes free-standing establishments that may have only one facility type as well as establishments with multiple facility types.)

- Conduct phone or mail surveys of establishments that are likely to contain one or more of these facility types.

Step 2 – Assign numbers to all establishments on the master establishment list from one (1) to whatever the total is.

As an example, let's say our master inventory list contains 1000 establishments. These establishments will be numbered from 1 to 1000.

Step 3 – Estimate the minimum sample size plus substitute pool for each of the facility types. When estimating the minimum sample sizes, if information is not available as to the facility types that may be present in a retail food establishment, it should be assumed that retail food stores have all four facility types. This is a conservative approach and will ensure that the sample size obtained will result in a statistically valid number of establishments.

In this example, we assume that the project planner estimates that each of the facility types will have an inventory greater than 373. Therefore, 87 establishments will be needed for EACH facility type to have a statistically valid study – (Reference Table 2 on page 12). The project planner also elects to randomly select 20 substitutes for each facility type.

Step 4 – (Optional Step) – Decide whether or not to oversample based on travel considerations. If planning travel routes across a wide area is necessary, then you may want to consider oversampling.

Step 5 – Randomly select numbers from the numbers assigned to the master list of establishments. For efficiency, select about 4 times the largest sample size plus the largest substitute pool. You will need this many numbers to be sure you have enough to create the lists described in the steps that follow.

In this example, we would select 4(87+20) = 428 establishment numbers, keeping note of the order in which they were selected.

Step 6 – Form an inspection-planning list of establishments with columns to indicate which departments are to be inspected.

An example of an inspection-planning list may look like this:

SELECTION ORDER	MASTER LIST SELECTION NUMBER	ESTABLISHMENT NAME	MEAT MARKET/ DEPT.	SEAFOOD STORE/ DEPT.	DELI STORE/ DEPT.	PRODUCE MARKET/ DEPT.
1						
2						
3						
4						
5						
6						
7						
8						
9						
Etc.						

Step 7 – In the order that the randomly selected establishments were chosen in Step 4, (not in the order on the master list) begin listing the establishments and determining which "facility types" (meat, seafood, deli, produce) are present. Use sequential numbers within each "facility type" column of the table in order to keep track of how many selections have been made. If it is not already known or obvious, research which "facility types" are located in each store, either from:

- an existing database containing an establishment inventory;
- information or records obtained during routine inspections; and/or
- telephone inquiries.

The following chart provides an example of an inspection planning list for meat, seafood, deli and produce facility types.

For example:

SELECTION ORDER	ESTABLISHMENT MASTER LIST NUMBER AND NAME	MEAT MARKET/ DEPT.	SEAFOOD STORE/ DEPT.	DELI STORE/ DEPT.	PRODUCE MARKET/ DEPT.
1	326 Luigi's Seafood	---	1	---	---
2	877 Rudy's Steaks	1	---	---	---
3	121 Big Food Store	2	2	1	1
4	398 General Store	3	3	---	2
5	614 Bob's Deli	---	---	2	---
.....	.....	.....	.....	.....	.....
92	32 Grocery Shop	87	73	---	76
93	459 Little Grocery	Sub-1	74	---	77
94	701 Sam's Seafood	---	75	---	---
95	222 Meaty Market	Sub-2	---	65	---
.....	.....	.....	.....	.....	.....
120	571 Sandy's Seafood	---	87	---	---
121	834 Finer Foods Inc.	Sub-13	Sub-1	83	87
122	991 Deli Delicious	---	---	84	---
123	143 Foods R Us	CLOSED	Sub-2	85	Sub-1
.....	.....	.....	.....	.....	.....
130	689 Produce Pantry	---	---	---	Sub-2
131	267 Super Grocers	.....	Sub-4	87	Sub-3
132	762 All Foods, Inc.	.....	Sub-5	Sub-1	Sub-4
Etc.	.....	.....	.....	.....	.....
TOTAL MINIMUM INSPECTIONS PER FACILITY TYPE		**87**	**87**	**87**	**87**

As establishments are listed, the running count for each facility type is noted in the respective columns until 87 are identified. Schedule inspections for the first 87 establishments within each facility type.

In this example, the project planner decided that 15 substitutes would be enough, so selections continue until 15 extra establishments are included as substitutes for each facility type demoted as "Sub-1", "Sub-2", etc.

Whenever you think your number of substitutes is adequate for a facility type, just stop checking for facility type. If the number of substitute selections for a facility type proves to be insufficient, additional ones can be added from where they stopped for that facility type on the inspection planning list. Continue to add establishments to the inspection planning list until all four facility types have the required number of planned inspections.

Approach 2 – For jurisdictions that can have well-defined establishment inventories for meat, seafood, deli and produce facility types and desire to use separate lists for each.

Jurisdictions that have well-defined establishment inventories have the option of sampling from separate inventory lists for each of the four retail food facility types (meat, seafood, deli and produce). This approach utilizes a well defined listing of each of the facility types whether they are part of a multi-department retail food store or a freestanding establishment.

If the same retail food store is randomly selected from two or more of the facility type lists (meat, seafood, deli or produce), those data collections can be done on the same visit. However, even when stores have all four departments, it is expected to be rare for the same store to be selected for more than one department. This approach, therefore, would be expected to require many more stores to be inspected due to the independent sampling from each of the four lists.

Step 1 – Assign numbers separately to all establishments for each of the four facility type inventories from one (1) to whatever their totals are.

Step 2 – Determine the minimum number of establishments needed for EACH facility type to have a statistically valid study using Table 2 on page 12.

For this example, each of the four facility types has an establishment inventory that is greater than 373.

Meat Markets/Departments	**650 establishments**
Deli Stores/Departments	**500 establishments**
Produce Markets/Departments	**450 establishments**
Seafood Stores/Departments	**400 establishments**

Therefore, 87 establishments will be needed for each facility type to have a statistically valid study.

Step 3 – **(Optional Step) –** Decide whether or not to oversample based on travel considerations. If travel time is not a major consideration, skip to Step 4. If planning travel routes across a wide area is necessary, then oversample by ten percent (10%) or more.

For this example, all of the establishment inventory is defined and readily accessible. Travel is not a consideration so the decision was made not to oversample.

Step 4 – From each facility type inventory, randomly select establishment numbers until the required sample and the pool of substitutes is attained. (If needed, substitute establishments will be used in the order they are selected to achieve the minimum number of inspections).

Based on our example:

- **87 random numbers from 1 to 650 will be selected for meat markets/departments;**
- **87 random numbers from 1 to 500 will be selected for deli stores/departments;**
- **87 random numbers from 1 to 450 will be selected for produce markets/departments; and**
- **87 random numbers from 1 to 400 will be selected for seafood stores/departments.**

For each of the four facility types, forty (40) additional numbers will also be selected for substitute establishments that might be needed. For each facility type duplicate numbers are discarded. Numbers will continue to be selected until 127 distinct numbers

have been attained for each facility type.

Step 5 – Conduct Baseline data collection at the randomly selected establishments.

For each facility type in our example, attempt 87 inspections. If less than 87 are successful, use substitute establishments in the order that they are selected until 87 inspections are completed.

TWO-STAGE RANDOM SAMPLING

Two-stage sampling can help a state when one or more of the following is true:

- the state needs to limit travel,
- the state wants to limit the number of jurisdictions that they must involve,
- the state doesn't have inventory lists for each jurisdiction and wants to avoid having to obtain all of them.

Other jurisdictions have no need to read this section. The individuals directly carrying out the selection of establishments should also read Annex IV, Section C.

STAGE 1

Step 1 – Decide the geographic area the Baseline will cover such as an entire state or a regional area. Within this area, identify geographic units that you will designate as primary sampling units (PSUs).

A. Your PSUs should combine to cover the total area to be represented in your baseline.
B. In some states, counties and/or cities will serve as good PSUs.
C. You must know the population count for each PSU.
D. Your PSUs should not overlap each other.

As an example, the chart on the next page is used to illustrate a state agency that has decided to conduct a state-wide Baseline using the counties located within the state as the primary sampling units (PSUs).

PRIMARY SAMPLING UNIT (PSU)	COUNTY	POPULATION	SELECTION RANGE
1	Morgan	250,000	1 to 250,000
2	Freeport	19,780	250,001 to 269,780
3	River	66,410	269,781 to 336,190
4	Milton	210,300	336,191 to 546,490
5	Lewis	107,640	546,491 to 654,130
6	Clarke	26,370	654,131 to 680,500
7	King	35,590	680,501 to 716,090
8	Rose	150,260	716,091 to 866,350
9	Greenbelt	81,130	866,351 to 947,480
10	Newport	52,520	947,481 to 1,000,000
11	Mason	18,005	1,000,001 to 1,018,005
12	Fulton	13,682	1,018,006 to 1,031,687
13	Warren	16,318	1,031,688 to 1,048,005
14	Parish	20,166	1,048,006 to 1,068,171
15	Dixon	9,834	1,068,172 to 1,078,005
16	Polk	17,879	1,078,006 to 1,095,884
17	Greenlee	12,121	1,095,885 to 1,108,005
18	Baldwin	6,403	1,108,006 to 1,114,408
19	Lexington	23,597	1,114,409 to 1,138,005
20	Central	11,995	1,138,006 to 1,150,000
STATE TOTAL		**1,150,000**	

For each county, a selection range based on population is provided in the fourth column. The selection ranges are determined by a sequential number order beginning with the first PSU, Morgan County, through the last PSU, in this example Central County. The number range for each PSU (county) is based on its population. This provides for the random selection of PSUs (counties) with probabilities proportional to their populations.

Step 2 – For each facility type, estimate the total establishment inventory for all the PSUs as either over 373 or some number less than 373. If less than 373, make an estimate of the size; when in doubt, estimate too large a number.

Step 3 – Use the estimated total establishment inventory to determine the minimum sample size for each facility type from Table 2 on page 12. If a minimum sample size is an odd number, increase it by 1 to make an even number. We call this the "desired sample size". **(Do not use over-sampling for two-stage sampling.)**

For our example, the State Department of Health is coordinating the development of a Baseline. The State Department of Health has entered into delegation agreements with the counties to conduct inspections of the facility types under their jurisdictions. In our example, the State Department of Health is not responsible for the regulatory oversight of retail food stores. This is done by the State Department of Agriculture. The State Department of Health has decided, therefore, to exclude meat, seafood, deli and produce facility types from their Baseline. Their Baseline will focus on the remaining 5 facility types (Hospitals, Elementary Schools, Nursing Homes, Fast Food Restaurants, and Full-Service Restaurants).

Facility Type	Inventory	Minimum Sample Size	Desired Sample Size
Hospitals	19	14	14
Elementary Schools	330	83	84
Nursing Homes	71	42	42
Fast Food Restaurants	>373	87	88
Full Service Restaurants	>373	87	88

In the above chart:

- **The Inventory column represents the estimated total number of establishments in all the PSUs (counties) for each facility types.**
- **The minimum sample size is obtained from Table 2, page 12 and is based on the estimated establishment inventory for each facility type.**
- **The "Desire Sample Size" is derived by adding 1 to any minimum sample size that may have been an odd number.**

Step 4 – For each facility type in Step 3, divide the desired sample size by 2. This will be the number of Primary Sampling Unit (PSU) selections to be made for that facility type.

For our example the PSU Selections column has been added to the chart in Step 3.

Facility Type	Inventory	Minimum Sample Size	Desired Sample Size	PSU Selections
Hospitals	19	14	14	**7**
Elementary Schools	330	83	84	**42**
Nursing Homes	71	42	42	**21**
Fast Food Restaurants	>373	87	88	**44**
Full Service Restaurants	>373	87	88	**44**

Step 5 – Using the chart in Step 4, we need to make 44 selections of PSUs (counties) based on the largest number of PSUs needed for any one of the facility types. 44 PSUs (counties) are needed in our example for Fast Food Restaurants and Full Service Restaurants. Select 44 random numbers from 1 to 1,150,000 (referring to the chart In Step 1, this selection range is needed because it represents the total population in the PSUs (counties) that will be part of the Baseline). Don't eliminate any duplicates; rather keep them.

Step 6 – Now, in the order that the random numbers were selected, determine where in the selection range, each random number lies. Each time one of the random numbers falls into a PSU's selection range, that PSU (county) is selected.

For example, if the first random number selected is 772,550, then PSU 8 has been selected.

PRIMARY SAMPLING UNIT (PSU)	COUNTY	POPULATION	SELECTION RANGE
1	Morgan	250,000	1 to 250,000
2	Freeport	19,780	250,001 to 269,780
3	River	66,410	269,781 to 336,190
4	Milton	210,300	336,191 to 546,490
5	Lewis	107,640	546,491 to 654,130
6	Clarke	26,370	654,131 to 680,500
7	King	35,590	680,501 to 716,090
8	**Rose**	**150,260**	**716,091 to 866,350**
9	Greenbelt	81,130	866,351 to 947,520

A summary of the randomly selected PSUs (counties) in the order they were chosen is presented below.

Order of Selection	Random Number	PSU (County) Selected		Order of Selection	Random Number	PSU (County) Selected
1	772,500	# 8 – Rose Co.		23	1,083,885	#16 – Polk Co.
2	409,905	# 4 – Milton Co.		24	201,089	# 1 – Morgan Co.
3	176,337	# 1 – Morgan Co.		25	1,140,423	#20 – Central Co.
4	398,646	# 4 – Milton Co.		26	693.546	# 7 – King Co.
5	19	# 1 – Morgan Co.		27	303,455	# 3 – River Co.
6	598,997	# 5 – Lewis Co,		28	988	# 1 – Morgan Co.
7	875,007	# 9 – Greenbelt Co.		29	1,061,835	#14 – Parish Co.
8	599,003	# 5 – Lewis Co.		30	851,234	# 8 – Rose Co.
9	299,999	# 3 – River Co.		31	905,652	# 9 – Greenbelt Co.
10	703,619	# 7 – King Co.		32	411,119	# 4 – Milton Co.
11	135,677	# 1 – Morgan Co.		33	672,468	# 6 – Clarke Co.
12	10,021	# 1 – Morgan Co.		34	360,003	# 4 – Milton Co.
13	431,455	# 4 – Milton Co.		35	551,115	# 5 – Lewis Co.
14	681,668	# 7 – King Co.		36	248, 311	# 1 – Morgan Co.
15	724,427	# 8 – Rose Co.		37	543, 498	# 4 – Milton Co.
16	334,442	# 3 – River Co.		38	999,171	#10 – Newport Co.
17	502,211	# 4 – Milton Co.		39	273,621	# 3 – River Co.
18	833,388	# 8 – Rose Co.		40	801,339	# 8 – Rose Co.
19	549,453	# 5 – Lewis Co.		41	653,192	# 5 – Lewis Co.
20	981,819	#10 – Newport Co.		42	1,024,518	#12 – Fulton Co.
21	1,146,098	#20 – Central Co.		43	534,539	# 4 – Milton Co.
22	1,048.010	#14 – Parish Co.		44	103,674	# 1 – Morgan Co.

Step 7 – Now put the first selected PSU on the list for all facility types, then the second, and so forth. Stop adding to each facility type list when you reach the desired number of PSU picks. (You will have picked some PSUs many times; these will be the highly populated ones.)

In our example, the randomly selected PSUs (counties) are assigned facility types as illustrated in the chart below.

PSUs (Counties) SELECTED AND ASSIGNED TO FACILITY TYPES

	FACILITY TYPE (Number of PSUs Needed)				
Order of Selection	**Hospitals (7)**	**Elementary Schools (42)**	**Nursing Homes (21)**	**Fast Food Restaurants (44)**	**Full Service Restaurants (44)**
1	PSU # 8	PSU # 8	PSU # 8	PSU # 8	PSU # 8
2	PSU # 4	PSU # 4	PSU # 4	PSU # 4	PSU # 4
....	....	....	....	....	....
7	PSU # 9	PSU # 9	PSU # 9	PSU # 9	PSU # 9
8	STOP	PSU # 5	PSU # 5	PSU # 5	PSU # 5
9		PSU # 3	PSU # 3	PSU # 3	PSU # 3
....	....	....	....	....	....
21		PSU #20	PSU #20	PSU #20	PSU #20
22		PSU #14	STOP	PSU #14	PSU #14
....	....	....	....	....	....
42		PSU #12		PSU #12	PSU #12
43		STOP		PSU # 4	PSU # 4
44				PSU # 1	PSU # 1

Step 8 – For the first facility type, note the set of PSUs selected and note how many times each PSU was selected. For each PSU, pick two establishments for each time it was selected

For our example, the chart below lists the PSUs (counties) in the left hand column. The number not contained in the parenthesis under each facility type designates the number of times that PSU (county) was randomly selected. The number contained within the parenthesis indicates the number of establishments that need to be inspected for each facility type within the corresponding PSU (county).

Number of Times a PSU (County) was Selected
(and Number of Establishments that will be Selected from within that PSU)

PSU	Hospitals	Elementary Schools	Nursing Homes	Fast Food Restaurants	Full Service Restaurants
#1 – Morgan Co.	2 (4)	7 (14)	4 (8)	8 (16)	8 (10)
#2 – Freeport Co.	---	---	---	---	---
#3 – River Co.	---	4 (8)	2 (4)	4 (8)	4 (8)
#4 – Milton Co.	2 (4)	7 (14)	4 (8)	8 (16)	8 (16)
#5 – Lewis Co.	1 (2)	5 (10)	3 (6)	5 (10)	5 (10)
#6 – Clarke Co.	---	1 (2)	---	1 (2)	1 (2)
#7 – King Co.	---	3 (6)	2 (4)	3 (6)	3 (6)
#8 – Rose Co.	1 (2)	5 (10)	3 (6)	5 (10)	5 (10)
#9 – Greenbelt Co.	1 (2)	2 (4)	1 (2)	2 (4)	2 (4)
#10 – Newport Co.	---	2 (4)	1 (2)	2 (4)	2 (4)
#11 – Mason Co.	---	---	---	---	---
#12 – Fulton Co.	---	1 (2)	---	1 (2)	1 (2)
#13 – Warren Co.	---	---	---	---	---
#14 – Parish Co.	---	2 (4)	---	2 (4)	2 (4)
#15 – Dixon Co.	---	---	---	---	---
#16 – Polk Co.	---	1 (2)	---	1 (2)	1 (2)
#17 – Greenlee Co.	---	---	---	---	---
#18 – Baldwin Co.	---	---	---	---	---
#19 – Lexington Co.	---	---	---	---	---
#20 – Central Co.	---	2 (4)	1 (2)	2 (4)	2 (4)
TOTAL PSUs	**7**	**42**	**21**	**44**	**44**
TOTAL NUMBER OF ESTABLISHMENTS ( ) TO BE INCLUDED IN BASELINE	**14**	**84**	**42**	**88**	**88**

From this chart, note that:

- **Seven PSUs (Freeport, Mason, Warren, Dixon, Greenlee, Baldwin and Lexington counties) were <u>not</u> selected. The State Department of Health will not have to obtain establishment inventories from these areas.**

- **In some cases a facility type may not be included as part of the assigned establishments for a PSU (county). Hospitals, for example, will not be assigned to River County and some other counties even though these PSUs (counties) will be collecting data from the other facility types.**

In this example, Morgan County (PSU#1) is assigned:

- **4 Hospitals,**
- **14 Elementary Schools;**
- **8 Nursing Homes;**
- **16 Fast Food Restaurants; and**
- **16 Full Service Restaurants.**

Fulton County (PSU#12), on the other hand, is assigned:

- **2 Elementary Schools,**
- **2 Fast Food Establishments, and**
- **2 Full Service Establishments.**

STAGE 2

Step 9 – From each PSU (county) that has been assigned a facility type, the establishments will be selected from its inventory. The simple random sampling methodology describe at the beginning of Chapter 4 can be used.

- **Define the establishment inventory for each of the facility types assigned to the PSU (county).**
- **Assign numbers to all establishments within each facility type inventory from one (1) to whatever the total is.**
- **From each facility type inventory, randomly select the establishment numbers until the total number of facilities (plus substitutes) assigned to the PSU (county) is attained.**

In this example, Morgan County (PSU#1) will randomly sample from their inventory to obtain:

- **4 Hospitals,**
- **14 Elementary Schools;**
- **8 Nursing Homes;**
- **16 Fast Food Restaurants; and**
- **16 Full Service Restaurants.**

Step 10 – Conduct Baseline data collections at the randomly selected establishments. If a substitute is needed, as in case of a selected establishment that is closed, use the pre-selected substitute establishments in order that they were selected.

Chapter 5 - Data Collection for the Baseline

KEY CONCEPTS PRESENTED IN THIS CHAPTER

This chapter presents some "Best Practices" to consider when selecting personnel to collect the baseline data and establish a sound inspection protocol.

- Data Collectors should meet the criteria in the *National Voluntary Retail Food Regulatory Program Standards*, Standard #2 – Trained Regulatory Staff. If this is not possible, the staff with the most experience and expertise in the assessment of retail food, institution and restaurant facilities should be selected.
- Data Collectors should receive guidance on the difference between assessing establishments for purposes of establishing a baseline and regulatory compliance (discussed later in this Chapter).
- Data Collectors should not be assigned establishments that are part of their normal regulatory compliance oversight responsibilities.
- Separate any baseline data collection efforts from regulatory compliance activities.

Data collection within establishments that have regulatory compliance actions pending should be postponed until 30 days after mitigation of any such regulatory compliance action.

SELECTION OF DATA COLLECTORS

Baseline data collectors should possess a strong working knowledge of:

- Foodborne illness risk factors
- Restaurant, retail food and institutional foodservice operations, and
- The *Food Code* and its application.

A meaningful baseline upon which to measure the occurrence of foodborne illness risk factor relies on a consistent approach to assessing observed food preparation procedures and practices in each of the facility types. It is recommended that data collectors meet the minimum curriculum; field training and standardization criteria contained in the *National Voluntary Retail Food Regulatory Program Standards*, Standard #2 – Trained Regulatory Staff.

Having data collectors that meet the criteria in Standard #2 is not a requirement but rather a *Best Practice* guideline. Some jurisdictions may not have personnel who have completed Food Code standardization. These jurisdictions will need to assess the qualifications and experience level of their staff to make a

determination as to their ability to apply a consistent and uniform approach during their assessments.

OBSERVATIONS FOR DATA COLLECTION

An important distinction to keep in mind when planning your own baseline is this:

> *The measurement of the status of foodborne illness risk factors is not the same as conducting a regulatory compliance inspection.*

There is a significant difference between the purpose of observations made as part of establishing a baseline and those that are made as part of a regulatory compliance inspection. For a compliance inspection, you can record the observations against broad *Food Code* provisions, such as cooking temperatures, and write in your report any items that are out of compliance.

Baseline data collection forms, however, are divided into sub-parts so direct statistical correlations can be attributed to specific practices. The FDA Baseline form, for example, contains eight separate data items pertaining to cooking. In essence, eight different types of observations can be made pertaining to the cooking process step. Rather than a determination being made whether cooking is IN or OUT of compliance, observations are used to produce statistical reports on measurable trends pertaining to cooking different types of food products. Data collectors must understand this difference, particularly if their past experience has been restricted to determining regulatory compliance.

ESTABLISH THE BASELINE INSPECTION PROTOCOL

Minimize potential bias in collecting data. As with most studies, field observations performed by a technically qualified "third party" or "independent" personnel generally minimize potential biases. Data collectors, therefore, would optimally be someone other than the individual normally responsible for conducting regulatory oversight inspections for a given selected establishment.

Separate Baseline Data Collection from Regulatory Inspections. A *Best Practice* approach would be to separate any data collection effort from regulatory compliance inspections or actions. Some jurisdictions will want to collect Baseline data information in conjunction with routine inspections because of resource limitations.

When a jurisdiction attempts to collect baseline data as part of routine inspections, special consideration must be given to how this information is obtained and recorded. If a jurisdiction's baseline form is different than their regulatory compliance form, the data collector will need to complete two separate forms when data collection is combined with an inspection. Since the data collection approach is likely to contain more data items to assess, the

methodology and approach used should be primarily directed toward the baseline.

After the observations are made, they can be recorded on the baseline form. The data collector then can make a determination as to which of those items should be also included as part of the regulatory inspection.

Postponing Data Collection when Regulatory Compliance Action is Pending. It is possible that there will be pending regulatory compliance actions against an establishment selected for the baseline. Data collection should not be conducted at establishments that are in the process of undergoing regulatory compliance actions. These establishments, however, should not be removed from the sampling list compiled for the baseline.

Such compliance actions could include formal hearings, permit suspension, court orders, injunctions, or closure notices. Data collection in establishments where compliance action is pending should simply be delayed until the pending regulatory compliance action has been resolved. It is recommended that a 30-day period after the regulatory compliance action has been mitigated be observed before any data collection for the baseline is done within the establishment.

A follow-up inspection conducted as a standard part of the regulatory agency's inspection program is not considered a regulatory compliance action. Baseline data collection can take place when a follow-up inspection is pending.

THE BASELINE DATA COLLECTION FORM

A jurisdiction may want to develop an appropriate baseline data collection form, or it may choose to use the FDA Baseline Data Collection Form. The FDA Baseline Data Collection Form, comprised of 42 individual data items, plus supplemental items, is presented in Annex V. The 1997 FDA Food Code is used as the standard against which the 42 data items are assessed using the FDA Baseline Data Collection Form.

For each of the 42 data items, a determination was made 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 is to be provided in the comment section on the data collection form for each OUT OF COMPLIANCE observation.
- **NO** = Item is NOT OBSERVED. The NO notation is used when an item is a usual practice in the food service operation, but the practice is not observed during the time of the inspection.
- **NA** = Item is NOT APPLICABLE. The NA notation is used when an item is not part of the food service operation.

Annex VI contains the marking instructions used for field observations conducted for the FDA Baseline Data Collection Form.

The same data collection form is used at each establishment and for each facility type. The use of "not applicable" or "not observed" in place of just leaving items not marked and assuming compliance, is another big difference between collecting observations of conditions and scoring an establishment's compliance. Using the marking options for "not observed" and "not applicable" will be necessary for statistical validity even if a jurisdiction chooses to design its own data collection form.

ADVANTAGES OF USING THE FDA DATA COLLECTION FORM

- Provides a data collection form that has been successful in assessing observations on the occurrence of CDC identified foodborne illness risk factors.
- Establishes a process for comparability with the FDA national baseline on measurement trends pertaining to foodborne illness risk factors.
- Allows for the opportunity to add items of specific interest to a jurisdiction without losing comparability.
- Provides an approach consistent with the FDA *Food Code* standardization process used for state and local regulatory food safety professionals.
- Contains a free companion software program, available in ACCESS, to analyze the data and produce statistical reports.
- Implements an approach familiar to FDA Regional Food Specialists allowing them to provide technical assistance.

POTENTIAL CHALLENGES WITH USING THE FDA DATA COLLECTION FORM

- Requires resources to orient and train staff not familiar with the form and the data collection process it supports.
- Presents a document that is specific to baseline data collection and is difficult to use simultaneously as a regulatory inspection tool.
- Expands data collected to items beyond what is already collected by jurisdictions during regulatory compliance work. May require additional resources to collect, input and analyze the data.
- Specifies standards from the FDA *Food Code* that may be different from jurisdictional needs.

ADVANTAGES OF JURISDICTIONS DEVELOPING THEIR OWN DATA COLLECTION FORM

- Allows development of a data collection tool specific to jurisdiction's perceived needs and priorities.
- Provides for direct assessment of the impact of intervention strategies for data items collected.
- Creates an opportunity to obtain "buy-in" from management and staff in the design and implementation of the project.
- Presents the possibility of incorporating inspectional findings as part of the baseline data that is assessed.

POTENTIAL CHALLENGES FOR JURISDICTIONS THAT DEVELOP THEIR OWN DATA COLLECTION FORM

- Requires human and financial resources be allocated to develop a data collection tool specific to program goals.
- Requires statistical expertise on staff or available to ensure that the design of the project produces valid and meaningful trends.
- Requires a financial investment to ensure that computer software is in place to analyze the data and produce reports on trends.
- Prevents comparability with national trends or other jurisdiction's baseline if there are deviations from the four principles of comparability discussed in Chapter 6 – Baseline Comparability.

Chapter 6 - Baseline Comparability

KEY CONCEPTS PRESENTED IN THIS CHAPTER

This Chapter will focus on four principles that must be followed to ensure comparability with FDA's national baseline on the occurrence of foodborne illness risk factors within retail food program facility types.

The four principles of comparability:

1. Retain the 42 data items in FDA's Baseline (1997 *Food Code* is the Standard).
2. Do not merge any of the 9 facility types.
3. Retain the four marking options for assessing individual data items – (IN; OUT; NO; NA).
4. Adding new data items, if desired, without altering the original 42 is acceptable.

INTRODUCTION TO BASELINE COMPARABILITY

A baseline measurement represents an investment of your time, and this discussion is intended to help you get some extra value from this investment. In addition to all the immediate, local uses for your baseline measurements, most of you will want to compare your baseline with that of other jurisdictions, including FDA's national baseline. This comparability will also contribute to measuring the occurrence of foodborne illness risk factors nationally. As you go about designing and carrying out your baseline measurements, there are several important principles that will give you comparability.

A summary of the principles of comparability are presented below. Annex VII, provides a thorough discussion of these principles.

FIRST PRINCIPLE – RETAIN THE 42 DATA ITEMS

The first principle is "Don't delete, alter, or merge any of the 42 risk-related items." There is always pressure to make data collection forms shorter and to reduce data elements to their minimum, and this pressure motivates some individuals to see if they could live without an item or two. It will be especially tempting to delete an item that doesn't fit your local code; for example, when your local temperature requirements are different from the *Food Code.* It does take some extra effort to record compliance with items that are not in your local code, but if you remove these *Food Code* items, you will lose comparability.

Merging risk items can change the overall compliance rate and the specific risk category rate, sometimes in opposite directions! It is almost certain to create some distortions.

Let's review an actual example of merging individual data items. The Conference for Food Protection (CFP) has developed a draft regulatory inspection form for regulatory retail food programs. The CFP Inspection Form merges some FDA's items under the risk factor "Pathogen Destruction". The CFP form combines 8 FDA cooking temperature items into one overall "cooking" temperature item. It also combines FDA's 4 rapid reheating for hot holding items into another single "reheating" temperature item.

Suppose we inspect Joe's Diner, using both FDA's Baseline Data Collection Form and the CFP Inspection Form. Also suppose that we are able to observe all 12 of these data items in action. Suppose Joe's Diner is In Compliance with 11 items but OUT of compliance on one item.

- FDA Baseline Data Collection Form would find Joe's Diner to be out of compliance on one of the 12 items and in compliance on the remaining 11 items. Therefore FDA would say that Joe's is 8 percent out of compliance for pathogen destruction.

- The CFP Inspection Form would find Joe's Diner out of compliance on one of 2 items and in compliance on the other item. Therefore this form would indicate that Joe's is 50 percent out of compliance for pathogen destruction.

Fifty percent is a lot different from 8 percent, yet both forms are correctly tabulated. They just don't give statistics that we can compare.

In general, when you merge items from the FDA Baseline Data Collection Form to reduce the complexity of your local form, you make your inventory look more out of compliance for whatever risk factor is involved.

SECOND PRINCIPLE – DO NOT MERGE ANY OF THE FACILITY TYPES

The second principle is "Don't merge any facility types." There are two types of facility mergers that could distort your baseline. In the first type, you might be tempted to merge two grocery store departments and treat them like a single department.

For example, if you merge the meat & poultry department with the seafood department, you would have a single meat, poultry, and seafood department. This has an understandable meaning, but the compliance rate of this merged

department would often be lower than the compliance rates of either the seafood department or the meat & poultry department.

In the above example, if an item were out of compliance in seafood but in compliance for meat & poultry, we would lose the information that the meat & poultry operation was in compliance. This fact would be overridden by the "OUT" score in seafood. A combined store department would always receive the worse of the two individual ratings.

To avoid this sort of distortion, and to be comparable to FDA's baselines, don't merge facility types.

THIRD PRINCIPLE – RETAIN THE FOUR OBSERVATION MARKINGS FOR DATA ITEMS

The third principle is to retain the four codes – IN, OUT, NA, NO in order to obtain a valid denominator for determining your "in compliance" and "out of compliance" items. It is especially important to keep the two codes for "not applicable" and "not observed". Most people are familiar with the use of the "not applicable" code.

The "not observed" code is much more uncommon and will not be appreciated unless you ensure that it is understood. If you drop the "NO" finding, then you will usually code an applicable item that could not be observed as "IN" compliance, because it was not observed to be out of compliance. In this situation, you no longer know what your "IN" compliance rates really mean.

Without knowing that your in-compliance findings are based on observations, you cannot present them as positive findings of good operations. You don't want to perform all this work and have your results reduced in value. Keep the codes for both "not observed" and "not applicable".

FOURTH PRINCIPLE – ADDING NEW ITEMS, IF DESIRED, WITHOUT ALTERING THE ORIGINAL 42 DATA ITEMS IS ACCEPTABLE

It is acceptable to add items to the original 42 data items that FDA included in its baseline. You might also want to expand the list of items, adding ones of special local interest. For example, you might have additional local code items or emphases on special types of foods.

You can always add your local items by expanding the set of data items. The key to comparability, though, is to retain the original 42 data items intact. Then for comparison purposes you can use the FDA subset of 42 items.

Chapter 7 – Field and Statistical Limitations

KEY CONCEPTS PRESENTED IN THIS CHAPTER

As with all field studies involving data analysis, some internal and external factors will influence 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

FIELD OPERATIONAL LIMITATIONS

Establishment type, the season of the year, the time of day the inspection is conducted, and the length of time available for each inspection are some of the factors that impact data collection.

The time of day the inspection is conducted and the length of the inspection are significant factors limiting an inspector's observations. Often the most desirable time of day to conduct inspections is early in the morning when most of the daily preparation occurs. Inspections conducted in the afternoon hours, therefore, may not be conducive to observing and documenting critical preparation steps.

In addition, the length of the inspection 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 are difficult to observe include:

- Food received at proper temperature;
- Cooking of beef roasts to 130°F (54°C) for 112 minutes;
- 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) within 6 hours; and
- PHF (from ambient ingredients) cooled to 41°F (5°C) or below in 4 hours;

These data items require a significant period of time to assess compliance with regard to time/temperature criteria or involve processes or operational steps that occur outside traditional regulatory work hours.

STATISTICAL LIMITATIONS

Precision of Percentages for Each Facility Type. Attempts will be made to observe the same 42 risk-related individual data items at each establishment selected for your baseline. Many times, some items will not be observed during inspections. For example, by the nature of their operations, meat and poultry departments are less likely to have risk factor occurrences than full-service restaurants that involve extensive food preparation.

The precision of the percentages calculated from the data is directly related to the number of observations included in the analyses. The more observations, the greater precision of the percentages.

Given the diversity within retail operations, it is anticipated that many individual data items will have relatively small numbers of observations. In designing your baseline, therefore, more emphasis should be given to analysis of the collection of data items within the 5 major risk factor categories.

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

It is more statistically reliable to group the data items into the risk factors because a larger pool of observations is attained. For any one of the 42 individual data items, the percentage IN COMPLIANCE is less precise due to the fewer number of observations available for analysis. The Report of the *FDA Retail Food Program Database of Foodborne Illness Risk Factors*, referenced in Chapter 1, provides a comprehensive discussion on statistical limitations associated with analyzing FDA's baseline data.

Within a single baseline, the sample sizes recommended in this manual are not large enough to support comparisons of subsets of the original samples. For example, the project is not designed to support comparisons of chains of fast food restaurants or chains of grocery stores.

By establishing a baseline, the information gathered form future field inspections can be used to measure trends in the active managerial control of foodborne illness risk factors. It is expected that an improvement in compliance with Food Code provisions that address these risk factors will have a direct impact on the occurrence of foodborne illness.

It is important to note that baseline data collection was not designed to determine an individual establishment's compliance with regulatory requirements. The

intent of establishing a baseline of current compliance with Food Code provisions that address CDC-identified foodborne illness risk factors is to track the change in the occurrence of risk factors through future comparison studies.. It is hoped that the implementation of regulatory and industry intervention strategies presented in the Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (web-site presented on page 5), will decrease the incidence of the occurrence of risk factors in retail food, restaurants and institutional food service settings.

Annex I – Categorization of Facility Types

A jurisdiction must decide what types of food service facilities are to be included in its baseline data collection effort and how the facilities will be grouped. Grouping establishments and completing separate baselines for each facility type will promote better recognition of trends associated with a particular type of operation. Establish facility type categories that allow similar facilities to be grouped in a meaningful way.

In establishing facility type categories for the National Baseline, FDA included three major food service industry segments: institutions serving highly susceptible populations, restaurants, and retail food stores. For institutions, facility types were defined according to the nature of the highly susceptible population served. For restaurants, the manner in which the food is prepared and served was the relevant distinction between facility types. For retail food stores, the type of food being sold was the basis for defining facility types.

Industry Segment	***Facility Types***
Institutional Food Service	Hospitals Nursing Homes & Assisted Living Facilities Elementary Schools
Restaurants	Fast Food Restaurants Full Service Restaurants
Retail Food Stores	Deli Departments Meat and Poultry Departments Produce Departments Seafood Departments

The following definitions may assist jurisdictions in categorizing establishments into one of the nine facility types established by FDA.

Institutional Food Service

This industry segment includes food service to high-risk populations such as the elderly/older adults, the very young, and/or immuno-compromised. Each facility type may include food service operations that prepare and serve food on-site, serve as central kitchens, or are satellite kitchens served by central kitchens. If a satellite kitchen is randomly selected for inspection, it is not necessary to also inspect the central kitchen that is providing the meals.

Hospitals: Food service operations that serve patients, staff, and hospital visitors in a traditional hospital setting. Individuals who are acutely ill or those who are immuno-compromised are a target population for data collection.

Nursing Homes & Assisted Living Facilities: Food service operations that serve highly susceptible populations living in a group care setting. The elderly (55+ years) is the target population for the data collection.

Elementary Schools: Food service operations that serve students from one or more grade levels from Pre-school through Grade 5. Young children are a target population for data collection.

Restaurants

Most establishments in this industry segment can be categorized according to the commonly understood distinctions between a full service and a fast food restaurant. For a few establishments, the appropriate category may not be as obvious. In these cases, one should use good judgment and the definitions below to assign the facility type. The criteria used for selection of facility type should be applied consistently.

Full Service Restaurants: Establishments typically characterized by the availability of table service and a wait staff. Buffet restaurants and cafeterias that prepare a variety of potentially hazardous foods and provide customer seating may also be categorized as full service restaurants.

Fast Food Restaurants: Establishments typically characterized by counter service and drive-thru operations. These establishments may or may not provide customer-seating areas. Food is typically prepared or cooked for immediate service with limited advance preparation or carry over of prepared food from one day to the next. These establishments are also referred to as quick service restaurants.

Retail Food Stores

The inventory of each of the four retail food store facility types should include individual departments that are part of a larger grocery store or supermarket, as well as freestanding specialty markets that may sell foods from only one of the categories.

Deli Departments (Delicatessens): The department in a retail food store where potentially hazardous foods such as luncheon meats and cheeses are sliced for the customer and where sandwiches and salads (such as potato salad and cole slaw) are prepared and displayed. Parts of a deli may also include:

- Salad bars and other food bars maintained by the deli department manager;
- Areas where meat or poultry is cooked and offered for sale as ready-to-eat;
- Pizza stands; and
- Limited bakery operations attached to or adjacent the deli.

A freestanding cheese shop should also be categorized as a deli.

Meat and Poultry Departments: The meat and poultry department in a retail food store as well as any freestanding meat market or butcher shop that sells raw meat or poultry directly to the consumer.

Seafood Departments: Seafood departments in retail food store stores and freestanding seafood markets that sell seafood directly to the consumer include the preparation and sale of raw and/or ready-to-eat seafood. In-store sushi bars should be considered as part of the seafood department for purposes of the data collection.

Produce Departments: An area or department where produce is cut, prepared, stored, or displayed. A produce department may include salad bars that are managed by the produce department manager, as well as juicers.

NOTE: Some salad bars are managed and operated as part of the deli department (see delis above). For data collection purposes, the salad bar is included with the department that is responsible for preparing the food items that will be offered at the salad bar. If the deli prepares the items for the salad bar, the salad bar is included as part of the data collection for the deli. If the produce department prepares the items for the salad bar, then include the data collection for the salad bar as part of the produce department.

Some retail food stores may combine department functions. In cases where there is little or no product handling it may be appropriate to classify a combined department as a single facility type. For example, if a meat department happens to include a seafood case but there is no trimming or filleting of the seafood prior its display, the seafood case may be considered to be part of the meat department rather than as a separate seafood department.

Annex II – Risk Categorization of Food Establishments

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.

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 excluding 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.

Annex III – Sample Size Recommendations

SAMPLE SIZE RECOMMENDATIONS FOR LOCAL GOVERNMENT RETAIL FOOD SAFETY BASELINES

(*For this Annex, you may find it helpful to have the FDA Baseline Data Collection Form available as it is referred to frequently in the course of this discussion*)

This annex will explain how FDA/CFSAN's Division of Mathematics statisticians arrived at their recommended table of minimum sample sizes for state and local baselines. In order to judge how satisfactory a particular sample size would be, we want to predict how close its results are likely to come to the conditions at the entire inventory of establishments.

For a local baseline for some facility types, the inventory of establishments is small enough that sample sizes can be smaller than those used in the FDA's national assessment. Local requirements should also be satisfied by a slightly less stringent requirement on confidence limits, which will also allow some reduction to sample sizes. These two facts will lead to the recommendations below.

A theoretical profile of a local government retail food establishment inventory is presented below:

FACILITY TYPE	ESTABLISHMENT INVENTORY
Hospital	6
Nursing Homes	36
Elementary Schools	48
Fast Food Restaurants	420
Full Service Restaurants	360
Retail Food (Grocery) Stores	180

We recommend sample sizes for inventories of these sizes and bigger.

The purposes of a local baseline would include the ability to:

- compare the locality to FDA's national baseline and other jurisdiction's profile by risk factors;
- identify the subset of the 42 items in the baseline that are most in need of improvement.

Of course states and local governments will want to see whether compliance with risk-based factors is improving or not over periods of several years. The local situation is different from FDA's however, because local authorities have frequent contact with most of their inventories every year, and so they have many more points for comparison than just a baseline measurement. The locality will observe its improvements and declines in more detail than a periodic baseline, and will know more rapidly how its efforts are succeeding.

There are many different goals that we could pursue that would lead to different sample size requirements. Pursuing the most difficult goal will automatically provide big enough samples to satisfy all the other goals. The most difficult goal is to identify those specific baseline items, out of FDA's 42 items, that are most in need of priority attention.

Of course everyone wants every risk-related item to be as in compliance as possible, but with limited resources it is good to tackle the factors that are the least in compliance. All of FDA's 42 items are directly connected to risk, so FDA highlighted the least in compliance items in its August 10, 2000 report. The 9 tables numbered 3 through 11 gave items deserving priority attention for each of the 9 facility types in our baseline. We expect some degree of similarity in most local baseline results, so we will look at those tables when planning our statistical criteria.

There is no single correct basis for setting a sampling plan for an operation like baseline measurement. We determined by consulting FDA's retail field specialists that some rough guidelines could be derived. In particular, we view an item that is in compliance more than 80 percent of the time to need improvement, but not as a priority; an item in compliance less than 60 percent of the time clearly deserves priority attention.

If we want to give priority attention to items whose compliance (measured by the whole inventory) is less than 60 percent in compliance, then we have to decide what a successful measurement will be. Many approaches are reasonable, but FDA used the following goal when determining its sample sizes relative to prioritizing items:

> *If a particular baseline item has a compliance rate of no more than 60 percent, we want to have a high level of confidence that our data will show a compliance rate that is no more than 70 percent.*

This means that we can treat data items that score in compliance at less than 60 percent as clear priorities and treat data item up to 70 percent in compliance also as a special concern. This objective can be referred to as the "60-70 objective", for convenience.

FDA's J. Schneidman has used statistical theory (the hypergeometric distribution, reference at end of Annex) to see how well various sample sizes meet the 60-70 objective.

We suggest a goal of 95% confidence that a particular item with 60% total compliance would not be found to have more than 70% compliance in the randomly selected sample. (This is less demanding than the 98.5% confidence of the 60-70 objective required for the national baseline, but we think it is justified by two facts: the consequences of an error are confined to one locality, and the locality would soon discover any such errors by their follow-up activities.) The table below shows how many compliance observations must result from the sampling in order to achieve this.

Note that in this working paper, the term "observations" refers to findings of "in compliance" or "out of compliance", but does not include "not applicable" or "not observed". The table below cannot be used directly, since we can't predict the number of observations that would be achieved if the entire inventory were attempted.

FOR ONE OF THE 42 ITEMS FOR A FACILITY BASELINE:

If this number of observations would result if the entire inventory were inspected:	10	20	30	40	50	60	70	80	90	100
Then this number of observations is needed from the partial sample:	9	16	22	28	29	32	38	38	39	42

FOR ONE OF THE 42 ITEMS FOR A FACILITY BASELINE (Table continued):

If this number of observations would result if the entire inventory were inspected:	150	175	200	225	250	300	350	400	450
Then this number of observations is needed from the partial sample:	48	49	52	55	58	58	58	58	58

How can we adapt the above relationship for observations to the relationship for establishments, using the results of the FDA baseline study? As was noted in Tables 3-to-11 of the *Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors*, many items are both applicable and observable at only a fraction of the inspections. This means that, for some particular item in the baseline, the numbers of establishments in the inventory really represent

smaller numbers of observations, and so we must take that into account when setting our desired sample sizes.

Tables 3-to-11 record, for the 9 individual facility types, a total of 55 mentions of baseline items that deserve the most priority for improvement. I would expect these tendencies to be reflected to a great extent in most localities, and so we will use them as a guide in judging just how much to "oversample" in order to get adequate numbers of observations for making important decisions.

When an item is much less than 60 percent in compliance, say less than 50 percent, it takes only a very small sample to give a result no more than 70 percent in compliance with 95 percent confidence. We want to take into account the sampling that will do a good job for items that score very near to 60 percent.

There were ten mentions of items that appeared to be between 58-62% in compliance, and they were observed at between 72 and 100 percent of the inspections, with an average of 87 percent of inspections. We want to be able to capture enough observations for all such items, and we know that there will be some sampling error involved that requires that we assume an even lower level of observations to have high assurance of coverage. Therefore, we will allow for the possibility that only 2/3 (67%) of the inspections yield observations.

For example, suppose a locality has 90 elementary schools. For an item of interest, we would suppose that there would exist a potential for 60 observations (2/3 of 90). For this number (60) of potential observations, our table above would require a sample of 32 observations. Using the 2/3 rule, we would sample 48 establishments (since 2/3 of 48 is 32).

But the example above is clearly over-simplified, since our sampling of 48 of the 90 schools could conceivably encounter as many as 48 or as few as 18 observations. This involves the second layer of sampling errors, the sampling that coincides with observable items and with non-observable ones. We will accept this oversimplification, however, for several reasons. First, the probabilities suggest that mistakes will be very few.

Second, we have picked a hardest case to represent the test that our sampling must satisfy. The FDA baseline items with 58-62% compliance averaged 87 percent observations, much higher than our conservative assumption of 67 percent, and so we have a cushion of over-sampling for these items.
Third, 45 out of 55 of the FDA items of concern were noticeably above or below 60 percent in compliance, and therefore we will not need such large samples in order to characterize them correctly. Taken together, with a little smoothing at the upper end, these three reasons cause us to support the following table of samplings based on inventory sizes:

ESTABLISHMENT INVENTORY MINIMUM SAMPLE SIZES

Inventory Size	Sample Size
<9	ALL
9	8
10 – 12	9
13	12
14 – 19	14
20 – 24	18
25 – 28	23
29 – 31	24
32 – 36	27
37 – 43	29
44 – 51	33
52 – 58	38
59 – 73	42
74 – 81	44
82 – 96	48
97 – 103	53
104 – 133	57
134 – 148	59
149 – 163	63
164 – 186	68
187 – 261	72
262 – 291	74
292 – 328	78
329 – 373	83
374+	87

This will give the following sample sizes for the theoretical example presented earlier in this Annex.

FACILITY TYPE	ESTABLISHMENT INVENTORY	SAMPLE SIZE
Hospitals	6	6
Nursing Homes	36	27
Elementary Schools	48	33
Fast Food Restaurants	420	87
Full Service Restaurants	360	83
Retail Food (Grocery) Stores	180	68
TOTALS	**1050**	**304**

This Annex represents CFSAN's best advice for sample sizes of inspections for local baseline studies.

Annex IV – Random Sampling Methodologies

SUPPLEMENTAL GUIDANCE ON RANDOM SAMPLING FOR BASELINE DATA COLLECTION

KEY CONCEPTS PRESENTED IN THIS ANNEX

This annex will provide some additional direction for those individuals who will be tasked with:

- making the lists of specific establishments to be inspected and
- designating the substitute establishments to be used when necessary.

A. SAMPLE SIZES AND OVER-SAMPLING

Table 2 in Chapter 3 of this manual has spelled out the minimum sample sizes needed for good statistical uses of the baseline data. The manual has also discussed the decisions that the baseline team must make about what conditions will permit collection of data. For example, decisions should be made in advance for what to do if the establishment is discovered to be temporarily closed for renovations or is in a compliance action status that would make collection unwise on the originally scheduled date. The decision could be to delay the collection or to replace that establishment with a substitute establishment.

Depending on those decisions, and relying on their own judgment, the baseline collecting team might want to include some over-sampling in their initial scheduling of establishments. This will reduce the chance that they will have to do additional scheduling at the end of the data collection period. It will also mean some extra data collection for some facility types, since the entire over-sample must get an attempt at inspection once it is selected.

Whether or not some over-scheduling is chosen, all the sampling activities should also be extended to pre-select a list of substitute establishments that will be used, in the order selected, whenever some additional data collections are needed beyond those originally scheduled.

B. THE COUNTY SCENARIO

What we call the “county” scenario applies not only to a county but also to any compact, continuous area for which a baseline is desired (e.g., a metropolitan area or two or more adjacent counties). If a county is participating in a statewide baseline, however, then this scenario will not apply.

We assume, in the county scenario, that it is not important to limit travel time, and that there will be lists of establishments from which the local officials can take samples for their baseline.

After long consideration of several options, we are certain that simple random sampling is a very good method, statistically and practically, for selecting the establishments to inspect.

Simple Random Sampling

Suppose a county needs to perform a baseline on 260 schools. The team will create a list of these schools numbered from 1 to 260. Based on the sample size table, the minimum required sample size is 72. We suppose that the team chooses to do 10 percent over-sampling for the initial schedule, so the target becomes 79 samples.

The preferred way of selecting the sample would be to proceed by choosing 79 distinct random numbers plus a sufficient set of substitute numbers between 1 and 260. One should use a random number generator (see below) or table that gives each number an equal probability of selection. If any numbers are chosen more than once, the team discards the repetitions and keeps choosing until they have reached the desired count of distinct numbers. These will indicate which schools on the sampling list should be scheduled for data collection.

After the initial schedule of 79 is attempted, the job is complete as long as at least 72 were eligible for collection and completed. If more than 72 could be completed, then all those will be included in the baseline. If more collections are needed to reach 72, the remaining random numbers will be taken from the list of substitute numbers.

Note that random number generators are readily available on spreadsheet software packages, such as EXCEL, and some scientific calculators. The simplest way of which we are aware would be to adapt the following example using EXCEL. (Although EXCEL also has a special computer routine for random number generation, it requires special installation in an upgrade. This amount of trouble is not repaid by the operational improvement for such limited uses as baseline sampling.)

<u>Example:</u> Suppose you would like to generate 100 different random numbers from the numbers between 1 to 260. Open EXCEL. You will see a blank spreadsheet. Follow these directions:

1. **Generate the random number column**.

    - Click on cell **A1**, type **Rand #**.
    - Click on cell **A2**, type **=trunc(rand( )*260+1)** then hit the enter key.
    - Click on cell **A2**, then click **Edit**; then click on **Copy** on the Edit pull down menu.
    - Click on **A3** and scroll down to at least row 301. (To scroll down hold left mouse key down while moving the curser down)
    - Click on **Edit**; then click on **Paste** on the Edit pull down menu.

2. **Keep the unique values in the random number column, and delete the repetitions of the same numbers.**

    - Click on **A** above cell A1.
    - Click on **Edit**; then click on **Copy** on the pull down menu.
    - Click on **Edit**; then click on **Paste Special** on the pull down menu; then click on the circle next to **Values** and click **OK**.
    - Click on **Data**; then on the pull down menu, point to **Filter**, then click on **Advanced Filter**.
    - In the Advanced Filter dialog box:
        1. Select **Copy to another location**.
        2. Make sure that List range says **$A$1:$A$301** (Or some number higher than 301).
        3. Click in the **Copy to** box and type **$C$1**.
        4. Click in the **Unique records only** box.
        5. Click **OK**.
    - Next delete column A by clicking on the **A**. Then go to the **Edit** pull down menu and select **Delete**. When column A is deleted, column C becomes column B.
    - Finally delete all of the extra numbers from row 102 and below in column B. (Click on cell **B102**, hold down the left mouse key, and scroll down to anywhere below the last number in column B. Then hit the **Delete** key.)

3. **Generate an index column (optional). For ease of using the printed list of random selections, you can create an index to tell you exactly what the order of selection was.**

    - Click on cell **A1**, type **Index**.
    - Click on cell **A2**, type **1**.
    - Click on cell **A3**, type **=A2 +1**. Hit enter key.
    - Click on cell **A3**, then click **Edit**; then click on **Copy** on the Edit pull down menu.
    - Click on cell **A4**, scroll down to row 101.
    - Click on **Edit**; then click on **Paste** on the Edit pull down menu.
    - Click on **A** above cell A1.
    - Click **Edit**, then click **Copy** on the pull down menu.
    - Click **Edit**, then click **Paste Special** on the pull down menu, and then click on the circle next to **Values** and click **OK**.
    - Hit **Esc** key.

Bonus: Now you have a list of 100 different randomly chosen numbers between 1 and 260. Suppose you needed a minimum sample size of 72, are not planning on oversampling, and had chosen 100 numbers to allow for any substitutes that you might need. You would have to attempt inspections at the establishments whose numbers are in the first 72 on the list. These are not the 72 smallest numbers, but rather the 72 first picked. If you added an index column as in Step 3 above, these would be the random numbers whose index numbers were between 1 and 72. The index numbers 73 to 100 will determine the order in which any substitutes will be used.

For a number of reasons, you might find it handy to re-sort the first 72 random numbers in order of the random numbers themselves. For example, this facilitates looking them up on the inventory list. Also, if the inventory list were grouped by several counties, the re-sorting would group the random numbers by the counties. Note that you would <u>not</u> want to re-sort substitute numbers, since these will be used strictly in the order that they were selected. If these advantages apply to your selection, you can easily achieve the re-sorting by using the following procedure:

- Click on the row number (at the extreme left side) of the first substitute. (In this example, the first substitute would have index number 73, and would lie in row 74.)
- Click on **Insert** and then **Rows** on the pull down menu.
- Now Click on the lower right corner of the bottom of the minimum sample of numbers (e.g., cell B73). Now hold the left clicker down and scroll up and across to the upper left corner of cell A1.

- Now Click on **Data**, then on **Sort** on the pull down menu. Then on the Sort menu, click on the arrow on the **Sort by** box and click on **Rand #**. Then click on **OK**.

Now you have the first 72 random numbers ordered from smallest to largest, and printed below them is the list of substitutes, still in the order selected.

If you do not personally have access to such spreadsheet software, we are confident that you can locate someone else in your county or state government who does and can assist you with generating random numbers.

You can also use a table of random numbers, and an entire book of random numbers can be purchased. Use different sections of the table for each sampling of numbers. In the example above, you would select sequences of three-digit numbers, discard any numbers greater than 260, and then eliminate duplicates.

Separate lists of random numbers should be prepared for each facility type. Additional complications will apply in the cases of sampling grocery departments using a combined list and when sampling the two restaurant types from a combined restaurant list. The reader should consult sections D and E below for more specific advice on those situations.

Scheduling the Inspections

The order of performing inspections can be flexible, provided the county attempts to inspect all of the establishments from the beginning of the selection list to the place on the selection list they wish to stop. We encourage the use of administrative records and other means to determine eligibility for inspection in order to optimize the scheduling of travel.

C. TWO STATE SCENARIOS: SIMPLE RANDOM SAMPLING AND TWO-STAGE SAMPLING

There are two distinct scenarios that confront states.

Simple Random Sampling

The simplest scenario is a state that can obtain statewide inventory lists and is willing to go anywhere in the state that a simple random sample sends them. In this scenario, simple random sampling, the state will act just as in the county scenario discussed above, except that establishments will be selected from statewide lists rather than county lists. A particular caution should be noted, however, whenever states have enlisted counties to do the inspections: if any establishment selected must be dropped from the sample, the state should

choose another establishment from the statewide list, a selection that could be in a different county.

Two-Stage Sampling

The second scenario is more complex, but the complexity might be worth the trouble if a state needs to limit travel or hopes to limit the number of jurisdictions with which they must interact in order to obtain the baseline. It's especially useful when

- a state is conducting baselines on more than one facility type;
- a state doesn't have inventory lists for each jurisdiction and wants to avoid having to obtain all of them.

Only states in these situations need to read the following section, "Two-stage Sampling". All others may skip ahead to section D, "Special Problems with Sampling Restaurants".

In the first stage of a two-stage sample design, we select from a list of geographic areas that we call "primary sampling units" (PSUs). Units can be defined any way that the state wishes, so long as they don't overlap, they combine to include the entire area to be studied, and the state has population estimates for each unit. In some states, counties would serve as good PSUs.

We will be picking two establishments for each time a PSU is selected, so first we need to determine how many establishments belong in our total sample. For each facility type, we make an estimate of its inventory size. If the estimate is over 373, then we don't need more precision than that. If the estimate is less than 373, we should either use a list (e.g., state-registered hospitals) or make a best estimate just a little bit high, to minimize the risk that we will under-estimate. Then we consult the table of minimum sample sizes for each facility type. If some of these sizes are odd numbers, we add one to get an even number. These sample sizes we will call our "desired sample sizes." For each facility type, we then divide its desired sample size by 2. This tells us how many PSU selections to make for that facility type.

PSUs will be selected with replacement. That is, when a PSU is selected, it is not eliminated from the PSU sampling list and may be selected again. At the conclusion of the first stage, you will have a list of the PSU selections in the order selected. This single list will be used for all facility types being studied by the 2-stage method, thus reducing travel costs. If any facility type requires fewer inspections than the greatest requirement (likely for hospitals), its samples will be based on the order in which the PSU selections occurred. Now for each facility type, sum up the number of times that each PSU was selected.

In the second stage, two establishments need to be selected for inspection for each PSU selection that occurred in the first stage. Establishments will be selected using simple random sampling (without replacement) from the list of establishments for that PSU. The sampling within a PSU is conducted just the same as the county scenario in section B above. (Do not use oversampling with this two-stage design because it requires a fixed sample size.)

Example. Suppose a state is large enough that the required sample size for each of its facility type studies is 87 and that it consists of 20 PSUs with populations that vary as shown below. It will need to select 88 establishments for each facility type, and these will follow from a first stage at which it makes 44 PSU selections. (There are only half as many PSU selections, because each selection will lead to a further selection of two establishments for each facility type.)

The 44 PSU selections will be chosen in proportion to their population. This can be accomplished as follows. First assign each PSU a "selection range" of as many distinct numbers as the PSU's population, starting with number 1 in the first PSU. Form a selection range table as illustrated on the following page.

SELECTION RANGE TABLE

PSU	Population	Selection Range
1	250,000	1 to 250,000
2	19,780	250,001 to 269,780
3	66,410	269,781 to 336,190
4	210,300	336,191 to 546,490
5	107,640	546,491 to 654,130
6	26,370	654,131 to 680,500
7	35,590	680,501 to 716,090
8	150,260	716,091 to 866,350
9	81,130	866,351 to 947,480
10	52,520	947,481 to 1,000,000
11	(counties	1,000,001 to ……
....	Averaging	
20	15,000 apiece)	……..… to 1,150,000
State Total	**1,150,000**	

Next proceed by choosing 44 random numbers from 1 to 1,150,000 (the total selection range) using a random number generator that is designed to give each number an equal probability of selection. If any numbers recur, they should be retained. Next determine where in the selection range, each random number

lies. Each time one of the random numbers falls into a PSU's selection range, that PSU is selected. For example, if the first random number selected is 772,550, then PSU 8 has been selected.

After the 44 PSU selections have been made, make a list of all the PSUs that were selected and determine the total times each was selected. Calculate the number of establishments to be taken from each PSU by multiplying the number of times it was selected by 2. At this juncture, if the state does not have complete lists by PSU, it need only contact the PSUs that were selected and ask them for lists. Then the state selects the appropriate number of establishments from each PSU inventory list by using simple random sampling.

For example, suppose PSU 4 was selected 8 times. Then 2 times 8 = 16 establishments (plus a pool of 10 for substitutes) will be selected from the PSU 4 establishment inventory list. Suppose the PSU 4 fast food restaurant sampling list has 809 establishments. The state could generate a list of 26 random numbers between 1 and 809. The state would attempt to collect data at the first 16 establishments. Suppose it turns out that only 14 of them could be inspected. Then the state would proceed to the first two substitute establishments on the list and attempt to inspect them.

Similarly, using a list of random numbers designated for the next facility type, the state would select 16 establishments plus a substitute pool, and so forth until all included facility types have lists of selected establishments and substitute pools from PSU 4. Then the state would conduct a similar process for each PSU that was selected at least once.

The order of performing inspections can be flexible, provided the state attempts to inspect all of the establishments from the beginning of the selection list to the place on the selection list they wish to stop. We encourage the use of administrative records and telephone calls to determine eligibility for inspection, whenever feasible, to optimize the scheduling of travel within a PSU. Additional complications will apply in the cases of sampling grocery departments using a combined list and when sampling the two restaurant types from a combined restaurant list. The reader is referred to sections D and E below for more specific advice on those situations.

When it comes time to analyze the baselines, there will be a price a state will pay for the reduction in travel that this design offers. Unlike simple random sampling, this design requires that a distinct sampling weight be calculated for each facility type in each PSU that is selected. Weights will be multiplied times all the zero-one observations in the computer analyses that calculate the state's results. This is because in this design, establishments will have different probabilities of selection. For example, if there are 3 nursing homes in one county of 100,000 people and 3 others in a county of 50,000 people, the ones in the more populous county stand a better chance of being in the sample.

The sampling weight for an establishment is the inverse of its probability of selection. However, after removing factors that are common to all the weights within a PSU for a specific facility type, the weights can be simplified as follows. The weight for each nursing home in Adams County (a PSU) is the ratio of two numbers, A/B, where A = number of Adams County nursing homes and B = Adams County population.

The weights depend on accurate establishment counts based on the PSU lists. Therefore, states using this design are encouraged to make an effort to remove duplicate listings and establishments that are out of business or ineligible due to low risk level, before beginning the sampling. If this is not practical, then the state will be assuming that such unusable entries on the PSU sampling lists will be distributed proportionally and thus will not effect the weighted results.

D. SPECIAL PROBLEMS WITH SAMPLING RESTAURANTS.

The FDA measured two separate baselines of restaurants: Fast Food and Full Service. These informal category names are just that—informal. The boundary between the two is not simple, and the distinctions are discussed in Section III.B. of this manual. We do not expect that many jurisdictions will have separate

inventory lists of Fast Food and Full Service restaurants; we expect that most inventories will be mixed together in a single list, perhaps along with establishments that fit neither category, such as very limited service in bars and gas stations. The following is guidance for efficiently sampling from such a combined list. States and counties that already have separate lists of Fast Food and Full Service restaurants can skip ahead to Section E.

Making separate lists. If the inventory of either type of restaurant could be less than 375, it might save resources to extract the fast food, full service, and miscellaneous establishments into three separate lists. (If working only from paper lists, one could number the fast food in red ink and the full service in blue ink, and thus get separate enumerations.) With separate sets of numbers, one would then do simple random sampling on each set of numbers and the combined list problem would be solved. The planners of the Baseline study should determine any over-sampling amount and the size of the pool for substitutes.

Making separate lists: Under two-stage sampling. With the ability to obtain separate PSU lists for both restaurant types, proceed as described in section C above. (Do not use oversampling with this two-stage design because it requires a fixed sample size).

Keeping a combined list. If the combined inventory is so large that separation into three lists is a significant burden, then the combined inventory can be used.

In this case the minimum sample size for each type will be 87. The planners will decide on any over-sampling amount and the size of the pool for substitutes, and this will determine the size of the two facility type lists that they will develop. Randomly selecting a long list of establishment numbers from the combined inventory, the planners would start with the first establishment selected and decide whether it is fast food, full service, or neither. (Inspection records or communication with the local authority would be necessary for some of these decisions.) If fast food or full service, then it is placed in the respective sample. This process would continue until both samples reach the desired lengths. If all the initial list of establishment numbers were used and one list were still short, more establishment numbers would be randomly selected.

Keeping a combined list under two-stage sampling. Assuming there is a combined inventory list in each PSU, repeat the type of process described in the above paragraph separately for each selected PSU. This will result in separate lists of fast food restaurants and full service restaurants to consider for sampling in each PSU. If specific counts of fast food restaurants and full service restaurants are not available on a PSU basis, assume they are proportional to total restaurants on the PSU inventory list. Then use as weights the ratio of total restaurants in the PSU to population in the PSU. (Do not use oversampling with this two-stage design because it requires a fixed sample size).

E. SPECIAL PROBLEMS WITH GROCERY STORE DEPARTMENT SELECTIONS

The FDA baselines included four departments of grocery stores and some independent specialty stores: delicatessens, produce, meat/poultry, and seafood. Because many departments are combined in different ways at different establishments, these baselines present special problems for sampling. We explain two approaches: a combined master list of stores and separate lists by facility type.

Approach 1 – Combined List of Retail Food Store Facility Types. A combined inventory list is one that includes both standard retail food stores that may include multiple departments and freestanding delis, seafood stores, butcher shops, produce markets, etc. By using a combined inventory list, jurisdictions can take advantage of the opportunity to visit multiple facility types (meat, seafood, deli and produce) when they are present in one retail food store. This approach could provide some efficiency in the use of resources available for the data collection.

A large jurisdiction such as a populous state might not have information about which grocery stores have which departments, and might not wish to undergo the effort to classify every grocery store in the state. Even if they did, they might want to get more departments inspected in visits to the same stores. In either case, the jurisdiction would form a combined list of stores, including all of the

stores in the categories it wishes to study (standard grocery stores plus possibly freestanding delis, freestanding seafood stores, freestanding butcher shops, and freestanding produce shops). Call this the “master list”.

For purposes of sample size determination, the inventory for each type would be estimated by the number of specialty stores of that type plus the number of grocery stores. This upper bound on the type inventory would determine the sample sizes, since the true inventory size is unknown. We will discuss the procedure as if the numbers of grocery stores plus the number of any specialty type exceeds 373, so that the jurisdiction would need the maximum sample, 87, for each type. (The same method would be adapted if any type’s sample size were smaller.)

The planners would randomly select a large number of establishment numbers from the master list. Then the following procedures would be used.

1. Form an inspection-planning list of establishments with columns to indicate which departments are to be inspected, as follows (example below). In the order that the random selections were chosen (not in the order on the master list), begin listing establishments and checking off the departments present. If it is not already known or obvious, research which departments each store has, either from a database, records, or by telephone.

2. Keep a tally of how many stores have been assigned for each department. When the tally of any department reaches 87, mark the following ones with an “S” for “substitute”. Whenever you think your number of substitutes is adequate for a facility type, just stop checking for that facility type.

   If the number of substitute selections for a facility type proves to be insufficient, additional ones can be added from where they stopped for that facility type on the establishment inspection planning list. Continue to add establishments to the inspection planning list until all four facility types have the required number of planned inspections.

Example of retail store department selections from a master list.

MASTER LIST SELECTION NUMBER	ESTABLISHMENT NAME	MEAT DEPT./ MARKET	SEAFOOD DEPT./ STORE	DELI DEPT./ MARKET	PRODUCE DEPT./ MARKET
1	Luigi's Seafood	---	1	---	---
2	Rudy's Steaks	1	---	---	---
3	Big Food Store	2	2	1	1
4	General Store	3	3	---	2
5	Bob's Deli	---	---	2	---
.....	.....	.....	.....	.....	.....
92	Grocery Shop	88	73	---	76
93	Little Grocery	Sub-1	74	---	77
94	Sam's Seafood	---	75	---	---
95	Meaty Market	Sub-2	---	65	---
Etc.					

3. **(Optional Step)** – If planning travel across a wide area is necessary, you may want to consider oversampling.

4. Schedule the store inspections for all the non-substitutes.

5. If after attempting the scheduled inspections, less than 87 inspections are achieved for any departments, inspect stores from the substitute lists. As done previously, use the substitutes in the order that they were selected.

Approach 1.1. – Using Combined Retail Food Store Facility Type Inventory Lists with two-stage sampling. Make the PSU selections based on population as usual. This determines the number of inspections required in each PSU. Then make combined master inventory lists for each PSU that is selected, and proceed as above, using substitutes from within the same PSUs that need them. (Do not use oversampling with this two-stage design because it requires a fixed sample size.)

If separate counts of the four grocery departments are not available on the entire PSU inventories, then use as weights the ratio of total stores in the PSU's master inventory to population in the PSU.

Approach 2 – Separate Inventory Lists by Retail Food Store Facility Type. If a jurisdiction has a well defined categorization of all its retail food story facility types (meat, seafood, deli and product), including freestanding establishments, then another option would be to use four separate lists - one for each of the four facility types. If the same multi-department retail food store is randomly selected from two or more facility type lists, those data collections can be done on the same visit. However, even when retail food stores have all four facility types, it is expected to be rare for the same store to be selected for more than one facility type. This approach, therefore, would be expected to require many more stores to be inspected, due to the independent sampling from each of the four separate facility type lists.

NOTE: Jurisdictions that have well defined categories for the facility types within their retail food stores can still use the combined list approach (Approach 1) presented earlier. The combined list approach would be expected to substantially reduce the number of establishments required to be visited.

Approach 2.1 – Separate Lists by Retail Food Store Facility Type with Two-Stage Sampling. If feasible and preferred, use separate retail food store facility type lists (meat, seafood, deli and produce) in each PSU selected. Then proceed as described in section C, independently for each facility type. (Do not use oversampling with this two-stage design because it requires a fixed sample size.)

Annex V – FDA Baseline Data Collection Form

FDA Baseline Data Collection Form

Date:
Time In: Time Out: Inspector:
Data Collected During:
Establishment: Manager:
Physical Address:
City: Industry Segment:
State: Zip: County: Facility Type:

Certified Food Protection Manager: YES NO

_____ 41°F. (5°C.) or _____45°F. (7°C.) or _____ 41°F. (5°C.) + 45°F. (7°C.) is the cold holding requirement for this jurisdiction.

STATUS OF OBSERVATIONS:

IN = Item found in compliance (**IN** Compliance marking must be based on actual observations)
OUT = Item found out of compliance (**OUT** of Compliance marking must be based on actual observations)
NO = Not observable (**NO** marking is made when the data item is part of the establishment's operation or procedures, OR is seasonal and is not occurring at the time of the inspection)
NA = Not applicable (**NA** marking is made when the data item is NOT part of the establishment's operation or procedures)

CDC RISK FACTORS

CDC RISK FACTOR - FOODS FROM UNSAFE SOURCE

FOOD SOURCE

STATUS **1. Approved Source**

IN OUT A. All food from Regulated Food Processing Plants/ No home prepared/canned foods
IN OUT NA B. All Shellfish from NSSP listed sources. No recreationally caught shellfish received or sold
IN OUT NA NO C. Game, wild mushrooms harvested with approval of Regulatory Authority

_____
_____
_____

STATUS **2. Receiving / Sound Condition**

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

_____
_____
_____

STATUS **3. Records**

IN OUT NA NO A. Shellstock tags/labels retained for 90 days from the date the container is emptied
IN OUT NA NO B. As required, written documentation of parasite destruction maintained for 90 days for Fish products
IN OUT NA C. CCP monitoring records maintained in accordance with HACCP plan when required

_____
_____
_____

CDC RISK FACTOR-INADEQUATE COOK

PATHOGEN DESTRUCTION

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

***(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).***
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 17 A. 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

_____

_____

_____

CDC RISK FACTOR - IMPROPER HOLD

LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

STATUS **6. Proper Cooling Procedure** ***(NOTE: Record any temperature above 41°F. (5°C.) on blank lines. Production documents as well as statements from managers, person-in-charge (PIC), and employees, regarding the time the cooling process was initiated, may be used to supplement actual observations.)***

IN OUT NA NO A. Cooked PHF 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.)***

_____

_____

_____

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 ≤ 41°F. (5°C.) or 4 days at ≤ 45°F. (7°C.)

IN OUT NA NO C. Opened Commercial container of prepared ready-to-eat PHF is date marked as required

IN OUT NA NO D. When time only is used as a public health control, food is cooked and served within 4 hours as required

_____
_____
_____

CDC RISK FACTOR-CONTAMINATED EQUIPMENT

PROTECTION FROM CONTAMINATION

STATUS 10. Separation / Segregation / Protection

IN OUT NA NO A. Food is protected from cross contamination by separating raw animal foods from raw ready-to-eat food and by separating raw animal foods from cooked ready-to-eat food

IN OUT NA NO B. Raw animal foods are separated from each other during storage, preparation, holding, and display

IN OUT C. Food is protected from environmental contamination – critical items

IN OUT NA NO D. After being served or sold to a consumer, food is not re-served

_____
_____
_____

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

_____
_____
_____

CDC RISK FACTOR-POOR PERSONAL HYGIENE

PERSONNEL

STATUS **12. Proper, Adequate Handwashing**

IN OUT NO A. Hands are clean and properly washed when and as required

_____
_____
_____

STATUS **13. Good Hygienic Practices**

IN OUT NO A. Food Employees eat, drink, and use tobacco only in designated areas / do not use a utensil more than once to taste food that is sold or served / do not handle or care for animals present. Food employees experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service or single-use articles

_____
_____
_____

STATUS **14. Prevention of Contamination From Hands**

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

_____
_____
_____

STATUS **15. Handwash Facilities**

IN OUT A. Handwash facilities conveniently located and accessible for employees
IN OUT B. Handwash facilities supplied with hand cleanser / sanitary towels / hand drying devices

_____
_____
_____

CDC RISK FACTOR - OTHER

FOREIGN SUBSTANCES

STATUS **16. Chemicals**

IN OUT NA A. If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw consumption
IN OUT B. Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items are properly identified, stored and used
IN OUT NA C. Poisonous or toxic materials held for retail sale are properly stored

_____
_____
_____

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 items (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.)***

I**N 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 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.

_____
_____
_____

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.

_____
_____
_____

STATUS **21. Cooling – Raw Shell Eggs**

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.

I**N 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.

_____
_____
_____

Annex VI – Marking Instructions for the FDA Baseline Data Collection Form & Food Code Reference Sheet

SHEET-MARKING INSTRUCTIONS
Retail Food Program Database of Foodborne Illness Risk Factor
Data Collection Form

Date:
Time In: Time Out: Inspector:
Data Collected During:
Establishment: Manager:
Physical Address:
City Industry Segment:
State: Zip: County: Facility Type:

Certified Food Protection Manager: **YES** **NO**

YES marking indicates that there is a food protection manager present at the time of inspection who has been certified through a CFP recognized program.

NO marking indicates that there are NO certified food protection managers in the establishment at the time of inspection OR certification has been obtained through a program **NOT** recognized by the Conference for Food Protection.

_____ 41°F. (5°C.) or _____45°F. (7°C.) or _____41°F. (5°C.) + 45°F. (7°C.) is the cold holding requirement for this jurisdiction.

STATUS OF OBSERVATIONS:

IN = Item found in compliance (**IN** Compliance marking must be based on actual observations)
OUT = Item found out of compliance (**OUT** of Compliance marking must be based on actual observations)
NO = Not observable (**NO** marking is made when the data item is part of the establishment's operation or procedures, **OR** is seasonal and is not occurring at the time of the inspection)
NA = Not applicable (**NA** marking is made when the data item is NOT part of the establishment's operation or procedures)

CDC RISK FACTORS
CDC RISK FACTOR - FOODS FROM UNSAFE SOURCE

FOOD SOURCE

STATUS **1. Approved Source**

_____ **A. <u>All food from Regulated Food Processing Plants/ No home prepared/canned foods</u>**

IN / OUT This item should be marked either IN or OUT. If it is marked OUT of compliance make notes as to why it is OUT of compliance.

_____ **B. <u>All Shellfish from NSSP listed sources. No recreationally caught shellfish received or sold</u>**

IN / OUT This item may be marked either **IN** or **OUT**. If it is marked **OUT** of compliance make notes as to why it is **OUT** of compliance.

NA This item is marked **NA** if no shellfish are sold at the establishment.

_____ **C. <u>Game, wild mushrooms harvested with approval of Regulatory Authority</u>**

IN / OUT This item may be marked either **IN** or **OUT**. If it is marked **OUT** of compliance make notes as to why it is **OUT** of compliance.

NA This item is marked **NA** if no game or wild mushrooms are sold at the establishment.

NO This item is marked **NO** if no game or wild mushrooms are in the facility at the time. Mark **NO** if game/ wild mushrooms are a seasonal or an occasional menu item but are not being used at the time of inspection.

STATUS **2. Receiving / Sound Condition**

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

IN / OUT This item may be marked **IN** or **OUT** of compliance on any one of the listed items. If the food is safe and unadulterated, but you are not able to check any temperatures of food during receiving or are not able to determine the condition of foods transported, mark the item **IN** compliance with an explanation on the lines below as to what the **IN** represents. If one or all the listed items are **OUT** of compliance, make appropriate notes as to why the item is marked out of compliance.

STATUS **3. Records**

_____ **A. <u>Shellstock tags/labels retained for 90 days from the date the container is emptied.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason it is marked **OUT** of compliance.

NA This item is marked **NA** if shell stock is not used in the establishment.

NO This item is marked **NO** when shellstock is a seasonal or occasional item and has not been sold or used within the establishment within the past 90 days or you were unable to determine from invoices or purchases records whether shellstock was used or sold within the past 90 days.

_____ **B. <u>As required, written documentation of parasite destruction maintained for 90 days for fish products.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if these types of fish products are not used in the establishment.

NO This item may be marked **NO** if fish products of this type are a seasonal or occasional item and no fish products of this type are in the facility during visit and you are unable to determine compliance through purchase records, on-site documentation or invoices.

_____ **C. <u>CCP monitoring records maintained in accordance with HACCP plan when required</u>.**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if these types of records are not required for the operation of the establishment.

CDC 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.*)**

_____ **A. <u>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</u>.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** when raw shell eggs are not used in the establishment, including raw shell eggs not used in recipes.

NO This item is marked **NO** if raw shell eggs are used in the establishment, but you are unable to determine the cooking temperature.

_____ **B. Comminuted Fish. Meats, Game Animals (commercially raised) cooked to 155°F. (68°C.) for 15 seconds**

IN / OUT This item may be marked **IN** or **OUT** of compliance for one or all of the types of meat, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if no comminuted meats are used in the establishment.

NO This item is marked **NO** if one or more types of meat are used, but you are unable to determine the cooking temperature for any of them.

_____ **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).***

IN / OUT This item may be marked **IN** or **OUT** of compliance for one or all of the types of meat, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** when roasts or formed roasts are not cooked in the establishment

NO This item is marked **NO** if one or more of these meat items are used, but you are unable to determine the cooking temperature for any of them.

_____ **D. Poultry; stuffed fish. stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing these items cooked to 165°F. (74°C.) for 15 seconds**

IN / OUT This item may be marked **IN** or **OUT** of compliance for one or all of the types of stuffed items or stuffing containing these items with notes made concerning the reason it is OUT of compliance.

NA This item is marked **NA** if none of the types of stuffed items or stuffing containing these items are used in the establishment.

NO This item is marked **NO** if one or more of these food items are used, but you are unable to determine the cooking temperature for any of them.

_____ **E. Wild game animals cooked to 165°F. (74°C.) for 15 seconds**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason it is **OUT** of compliance.

NA This item is marked **NA** if no wild game animals are used in the establishment.

NO This item is marked **NO** if wild game animals are used, but you are unable to determine the cooking temperature for any of them.

_____ **F. <u>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.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if raw animal foods are not cooked in a microwave.

NO This item is marked **NO** if raw animal foods are cooked in a microwave but you are unable to determine the cooking temperatures during your inspection.

_____ **G. <u>Pork, Ratites and injected meats are cooked to 155°F. (68° C.) for 15 seconds.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance for one or all of the foods listed, with notes made concerning the reason it is marked OUT of compliance. **(*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 number 17. Please Make notes in the comment section.)***

NA This item is marked **NA** if NONE of the listed foods are cooked in the establishment

NO This item is marked **NO** if one or more of the listed foods are cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

_____ **H. <u>All other PHF cooked to 145°F. (63°C.) for 15 seconds.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked OUT of compliance.

NA This item is marked **NA** if no other PHF foods are cooked in the establishment

NO This item is marked **NO** if one or more of the food types for this category are cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

STATUS **5. Rapid Reheating For Hot Holding**

_____ **A. <u>PHF that is cooked and cooled on premises is rapidly reheated to 165°F (74°C.) for 15 seconds for hot holding</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if foods are not held over for a second service.

NO This item is marked **NO** if foods are held over for a second service, but you are unable to check the reheating procedure. Do not depend solely on discussions with management or cooks to make a determination on this item.

_____ **B. Food reheated in a microwave is heated to 165°F. (74° C.) or higher.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if foods are not reheated in a microwave in the establishment.

NO This item is marked **NO** if foods are reheated in a microwave but you were unable to make a determination of compliance.

_____ **C. Commercially processed ready to eat food reheated to 140°F. (60°C.) or above for hot holding.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if commercially processed ready to eat foods are not reheated in the establishment.

NO This item is marked **NO** if commercially processed ready to eat foods are reheated in the establishment but you were unable to make a determination of compliance.

_____ **D. Remaining unsliced portions of roasts are reheated for hot holding using minimum oven parameters.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if remaining unsliced portions of beef roasts are not used or reheated in the establishment.

NO This item is marked **NO** if remaining unsliced portions of beef roasts are reheated in the establishment, but you were unable to make a determination of compliance.

CDC RISK FACTOR - IMPROPER HOLD

LIMITATION OF GROWTH OF ORGANISMS OF PUBLIC HEALTH CONCERN

(NOTE: Record any temp 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.)

STATUS **6. Proper Cooling Procedure**

_____ **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 This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked NA if the establishment is a cook-serve establishment type or does not cool or reheat food.

NO This item is marked **NO** if the establishment does cool PHF for a second service, but you were unable to make a determination of compliance.

_____ **B. PHF is cooled to 41°F (5°C.) or below within 4 hours (prepared from ingredients at ambient temperature)**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if the establishment has no PHF that are prepared from ingredients at ambient temperature.

NO This item is marked **NO** if these types of foods are prepared, but you were unable to make a determination of compliance.

_____ **C. Foods received at a temperature according to Law are cooled to 41°F (5°C.) within 4 hours.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked NA if the establishment does not receive raw shell eggs, shellstock, milk or other products that have a transport temperature above 41°F. (5°C.).

NO This item is marked **NO** if the establishment does receive raw shell eggs, shellstock, milk or other products that have a transport temperature above 41°F. (5°C.), but you were unable to determine if these products were cooled down as described above.

STATUS **7. Cold Hold**

(*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.)*

_____ **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.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked OUT of compliance.

STATUS **8. Hot Hold**

(NOTE: If one product is found out of temperature the item is marked OUT of compliance. Record all temperatures taken.)

_____ 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 8.A. but IN under supplemental item number 18A. Record actual product and measured temperatures taken.)*

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if there is no PHF hot holding in the establishment.

NO This item is marked **NO** only in rare instances when you are unable to determine compliance. Inspections should be conducted during a time when hot holding temperatures can be taken.

_____ **B. Roasts are held at a temperature of 130°F (54°C.) or above**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if roast is not a menu item.

NO This item is marked **NO** only when you are unable to determine compliance. Inspections should be conducted during a time when hot holding temperatures can be taken.

STATUS **9. Time**

_____ **A. <u>Ready-to- eat PHF held for more than 24 hours is date marked as required (prepared on site)</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if there are no RTE PHF held for more than 24 hours

NO This item is marked **NO** when RTE PHF are held for more than 24 hours and you are unable to determine compliance. Do not depend solely on information from managers or cooks.

_____ **B. <u>Discard RTE PHF and/or opened commercial container exceeding 7 days at < 41°F. (5°C.) or 4 days at < 45°F. (7°C.).</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA**, such as when there is no RTE PHF prepared-on-premises, or opened commercial container held for more than 24 hours.

NO This item is marked **NO** if no date marking is done in the establishment and you are unable to determine compliance based on other information provided by PIC, manager or employees.

_____ **C. <u>Opened commercial container of prepared ready-to-eat PHF is date marked as required.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if there are no commercially prepared RTE PHF held.

NO This item is marked **NO** when commercially prepared RTE PHF are date marked and you are unable to determine compliance. Do not depend solely on information from managers or cooks.

_____ **D. <u>When time only is used as a public health control, food is cooked and served within 4 hours as required.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** if time is not used as a public health control.

NO This item is marked **NO** when time is used for a public health control and you are unable to determine compliance. Do not depend solely on information from managers or cooks.

CDC RISK FACTOR-CONTAMINATED EQUIPMENT

PROTECTION FROM CONTAMINATION

STATUS **10. Separation / Segregation / Protection**

_____ **A. <u>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.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA**, such as when there is a vegetarian menu or only commercially pre-cooked animal foods are used.

NO This item is marked **NO** when raw animal foods are used or served seasonally and you are unable to determine compliance.

_____ **B. <u>Raw animal foods are separated from each other during storage, preparation, holding, and display.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item is marked **NA** when there are NO raw animal foods used or only one raw animal species is used

NO This item is marked **NO** when raw animal foods are used or served seasonally and you are unable to determine compliance.

_____ **C. <u>Food is protected from environmental contamination – critical items.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

_____ **D. <u>After being served or sold to a consumer, food is not re-served.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. ***(NOTE: Actual observation of the disposition of unwrapped/unprotected, served food being returned to the kitchen must be made.)***

NA This item may be marked **NA** for retail operations for which there is no opportunity for re-service of foods, such as carry-out service only in restaurants or meat, produce and seafood depts. within retail food stores.

NO This item may be marked **NO** if you are not able to observe the disposition of unwrapped/unprotected foods after they have been served to the public and returned to the kitchen or food preparation area.

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.)

_____ **A. <u>Food contact surfaces and utensils are clean to sight and touch and sanitized before use</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance with notes made concerning the reason if it is marked **OUT** of compliance.

CDC RISK FACTOR-POOR PERSONAL HYGIENE

PERSONNEL

STATUS **12. Proper, Adequate Handwashing**

(NOTE: Maximum effort must be made to observe all sections of PERSONNEL.)

_____ **A. <u>Hands are clean and properly washed when and as required.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. This item must be marked **OUT** of compliance if one person is observed with dirty hands or hands that have not been properly washed as required.

NO This item may be marked **NO** for retail operations only in the case where no food workers are present to observe, such as a retail food store produce section where the display aisle has been fully stocked prior to the inspection.

STATUS **13. Good Hygienic Practices**

_____ **A. <u>Food Employees eat, drink, and use tobacco only in designated areas / do not use a utensil more than once to taste food that is sold or served / do not handle or care for animals present. Food employees experiencing persistent sneezing, coughing, or runny nose do not work with exposed food, clean equipment, utensils, linens, unwrapped single-service or single-use articles</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. This item must be marked **OUT** of compliance if one person is observed to be out of compliance with this item.

NO This item may be marked **NO** for retail operations only in the case where no food workers are present.

STATUS **14. Prevention of Contamination From Hands**

_____ **A. <u>Employees do not contact exposed, ready-to-eat food with their bare hands.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. This item must be marked **OUT** of compliance if one person is observed to be out of compliance with this item. ***(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.)***

NA This item may be marked **NA** for facilities that do not prepare ready-to-eat foods, such as retail meat or seafood department.

NO This item may be marked **NO** for retail operations that prepare ready-to-eat foods only in the case where no food workers are present.

STATUS **15. Handwash Facilities**

_____ **A. <u>Handwash facilities conveniently located and accessible for employees.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.

_____ **B. <u>Handwash facilities supplied with hand cleanser / sanitary towels / hand drying devices</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

CDC RISK FACTOR - OTHER

FOREIGN SUBSTANCES

STATUS **16. CHEMICAL**

_____ **A. <u>If used, only approved food or color additives. Sulfites are not applied to fresh fruits and vegetables intended for raw consumption.</u>**

IN This item is marked **IN** compliance if no unapproved additives are on site; or if sulfites are on the premises, but they are used properly.

OUT This item is marked **OUT** of compliance if unapproved additives are found on premises or approved additives are improperly used, i.e. on fresh fruits & vegetables.

NA This item is marked **NA** if the food establishment does not use any additives.

_____ **B. <u>Poisonous or toxic materials, chemicals, lubricants, pesticides, medicines, first aid supplies, and other personal care items properly identified, stored and used.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance. It may be marked **OUT** of compliance for improper storage or use of any one of the listed items.

_____ **C. <u>Poisonous or toxic materials held for retail sale are properly stored.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. It may be marked **OUT** of compliance for improper storage or use of any one of the items.

NA This item may be marked **NA** if the establishment does not hold 'poisonous or toxic materials for retail sale'.

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 items (contained in Section 1 – 16) that were assessed as part of the original baseline.)***

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

_____ **A. <u>Pork is cooked to 145^{o}F. (63°C.) or above for 15 seconds.</u>** ***(NOTE: Final cooking temperatures of Pork Roasts are recorded under data item 4C.)***

IN / OUT This item may be marked **IN** or **OUT** of compliance for pork, with notes made concerning the reason it is marked **OUT** of compliance. Please make note of actual temperature in the comment section.

NA This item may be marked **NA** if pork is not cooked in the establishment

NO This item may be marked **NO** if pork is cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

_____ **B. <u>Ratites and injected meats are cooked to 155^{o}F. (68°C.) or above for 15 seconds.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance for ratites or injected meats, with notes made concerning the reason it is marked **OUT** of compliance. Make notes of actual temperatures in the comments section.

NA This item may be marked **NA** if no ratites or injected meats are prepared in the establishment.

NO This item may be marked **NO** ratites or injected meats are cooked in the establishment, but you are unable to determine the cooking temperature during your visit.

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

_____ **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.)

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance.

NA This item may only be marked **NA** if there is no PHF hot holding in the establishment.

NO This item should be marked **NO** only in rare instances, when you are unable to determine compliance. Inspections should be conducted during a time when hot holding temperatures can be taken.

STATUS **19. Employee Health Policy**

_____ **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.**

IN / OUT This item must be marked **IN** or **OUT** of compliance, with notes made concerning the reason if it is marked **OUT** of compliance. ***(NOTE: In order to mark this item IN the establishment must have a WRITTEN employee health policy.)***

STATUS **20. Treating Juice**

_____ **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.**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason it is marked **OUT** of compliance.

NA This item is marked **NA** when juice is not packaged in the food establishment.

STATUS **21. Cooling – Raw Shell Eggs**

_____ **A. <u>After receiving, raw shell eggs are immediately placed under refrigeration that maintains ambient air temperature of 45°F. (7°C.) or less.</u>**

IN / OUT This item may be marked **IN** or **OUT** only if you are there to observe receipt of raw shell eggs and their disposition.

NA This item is marked **NA** when the establishment does not receive raw shell eggs.

NO This item is marked **NO** only when raw shell eggs are received but you are not there to observe their actual receipt and immediate disposition OR raw shell eggs are only a seasonal item,

STATUS **22. Cold Holding – Raw Shell Eggs**

_____ **A. <u>After receipt, raw shell eggs are stored in refrigerated equipment that maintains ambient air temperature of 45°F (7°C.) or less.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason it is marked **OUT** of compliance.

NA This item is marked **NA** when the establishment does NOT receive raw shell eggs.

NO This item is marked NO when raw shell eggs are received but there were no raw shell eggs on the premises at this time and you were unable to determine compliance. Additionally NO is marked when raw shell eggs are a seasonal or a limited use item within the establishment and none are on the premises at the time of your inspection.

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.)

_____ **A. <u>Prepackaged juice/beverage containing juice with a warning label (21 CFR, Section 101.17(g)) not served.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.

NA This item is marked **NA** if no highly susceptible population is served or if the facility does not serve any juice.

NO This item is marked **NO** if juice is served to a highly susceptible population, but no juice or packages containing juice are present within the establishment to verify compliance.

_____ **B. <u>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.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.

NA This item is marked **NA** if no highly susceptible population is served or if eggs are not served

NO This item is marked **NO** if eggs are used in the preparation of foods in an establishment that serves a highly susceptible population and the preparation of eggs is not observed and no eggs or pasteurized egg /pasteurized egg products are in the establishment

_____ **C. <u>Raw or partially cooked animal food and raw seed sprouts not served.</u>**

IN / OUT This item may be marked **IN** or **OUT** of compliance, with notes made concerning the reason if marked **OUT** of compliance.

NA This item is marked **NA** if raw or partially cooked animal food or raw seed sprouts are not prepared for service within an establishment that services a highly susceptible population.

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

1997 FOOD CODE

<table>
<tr><th>CDC Risk Factor
FOODS FROM UNSAFE SOURCES
Food Source</th><th>CDC Risk Factor
INADEQUATE COOK
Pathogen Destruction</th></tr>
<tr><td>1. Approved Source

<u>Data Item - 1A</u>
3-201.11* Compliance with Food Law
3-201.12* Food in A Hermetically Sealed Container.
3-201.13* Fluid Milk and Milk Products

<u>Data Item – 1B</u>
3-201.14* Fish
3-201.15* Molluscan Shellfish
3-202.18* Shellstock Identification

<u>Data Item – 1C</u>
3-201.16* Wild Mushrooms
3-201.17* Game Animals

2. Receiving/Sound Condition

<u>Data Item – 2A</u>
3-202.11* Temperature
3-202.15* Package Integrity
3-101.11* Safe, Unadulterated, and Honestly Presented</td><td>4. Proper Cooking Temperature per PHF

<u>Data Item – 4A</u>
3-401.11(A)(1)(a)* Raw Animal Foods
3-401.11(A)(2)* Raw Animal Foods

<u>Data Item – 4B</u>
3-401.11(A)(2)* Raw Animal Foods

<u>Data Item – 4C</u>
3-401.11(B)(1)(2)* Raw Animal Foods

<u>Data Item – 4D</u>
3-401.11(A)(3)* Raw Animal Foods

<u>Data Item – 4E</u>
3-401.11(A)(3)* Raw Animal Foods

<u>Data Item – 4F</u>
3-401.12* Microwave Cooking

<u>Data Item – 4G</u>
3-401.11(A)(2)* Raw Animal Foods

<u>Data Item – 4H</u>
3-401.11(A)(1)(b)* Raw Animal Foods</td></tr>
<tr><td>3. Records

<u>Data Item – 3A</u>
3-202.18* Shellfish Identification
3-203.12* Shellfish Maintaining Identification

Data Item – 3B
3.402.11* Parasite Destruction
3.402.12* Records, Creation and Retention

<u>Data Item – 3C</u>
3-502.12* Reduced Oxygen Packaging, Criteria
8-103.12* Conformance with Approved Procedures</td><td>5. Rapid Reheating for Hot Holding

<u>Data Item 5A</u>
3-403.11(A)* Reheating for Hot Holding

<u>Data Item 5B</u>
3-403.11(B)* Reheating for Hot Holding - Microwave

<u>Data Item 5C</u>
3-403.11(C)* Reheating for Hot Holding – Commercially Processed RTE Food

<u>Data Item 5D</u>
3-403.11(E)* Reheating for Hot Holding – Remaining sliced portions roasts Of beef</td></tr>
</table>

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

1997 FOOD CODE

<table>
<tr><th>CDC Risk Factor
IMPROPER HOLD
Limitation of Growth of Organisms
of Public Health Concern</th><th>CDC Risk Factor
IMPROPER HOLD
Limitation of Growth of Organisms
of Public Health Concern</th></tr>
<tr><td>6. Proper Cooling Procedure

<u>Data Item 6A</u>
3-501.14(A)* Cooling – Cooked PHF

<u>Data Item 6B</u>
3-501.14(B)* Cooling – PHF prepared from ingredients at ambient temperature

<u>Data Item 6C</u>
3-501.14(C)* Cooling – PHF receipt of foods allowed at >41° F. (5° C.) during shipment</td><td rowspan="2">9. Time

<u>Data Item 9A</u>
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 if preparation and is:
(1) ≤ 7 calendar days at 41° F. (5° C.) or less; or
(2) ≤ 4 calendar days at 45° F. (7° C.))

<u>Data Item 9B</u>
3-501.18* Ready-to-Eat, PHF, Disposition
(Food shall be discarded if not consumed within ≤ 7 calendar days at 41° F. (5° C.) or less; or ≤ 4 calendar days at 45° F. (7° C.))

<u>Data Item 9C</u>
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) ≤ 7 calendar days at 41° F. (5° C.) or less; or
(2) ≤ 4 calendar days at 45° F. (7° C.))

<u>Data Item 9D</u>
3-501.19* Time as a Public Health Control</td></tr>
<tr><td>7. Cold Hold (41° F. (5° C.))

<u>Data Item 7A</u>
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 <u>all</u> PHF that are maintained/held cold.)</td></tr>
<tr><td>8. Hot Hold (140° F. (60° C.))

<u>Data Item 8A</u>
3-501.16(A)* PHF, Hot and Cold Holding

<u>Data Item 8B</u>
3-501.16(A)* PHF, Hot and Cold Holding</td><td></td></tr>
</table>

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

1997 FOOD CODE

<table>
<tr><th>CDC Risk Factor
CONTAMINATED EQUIPMENT
Protection from Contamination</th><th>CDC Risk Factor
POOR PERSONAL HYGIENE
Personnel</th></tr>
<tr><td>10. Separation / Segregation /Protection

<u>Data Item 10A</u>
3-302.11(A)(1)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation
(Separate raw animal foods from raw RTE and cooked RTE foods)

<u>Data Item 10B</u>
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)

<u>Data Item 10C</u>
3-302.11(A)(4-6)* Packaged and Unpackaged Food – Separation, Packaging, and Segregation
3-304.11(B)* Food Contact with Equipment and Utensils

<u>Data Item 10D</u>
3-306.14(A)(B)* Returned Food, Reservice or Sale</td><td>12. Proper, Adequate Handwashing

<u>Data Item 12A</u>
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

<u>Data Item 13A</u>
2-401.11* Eating, Drinking, or Using Tobacco
2-401.12* Discharges from the Eyes, Nose and Mouth
2-403.11* Handling Prohibition – Animals
3-301.12* Preventing Contamination when Tasting

14. Prevention of Contamination from Hands

<u>Data Item 14A</u>
3-301.11* Preventing Contamination from Hands</td></tr>
<tr><td>11. Food Contact Surfaces

<u>Data Item 11A</u>
4-601.11(A) & (B)* Equipment, Food Contact Surfaces and Utensils
4-602.11* Equipment Food-Contact Surfaces and Utensils - Frequency
4-701.10* Sanitization of Equipment and Utensils – Food Contact Surfaces and Utensils
4-702.11* Sanitization of Equipment and Utensils – Before Use After Cleaning</td><td>15. Handwash Facilities

<u>Data Item 15A</u>
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

<u>Data Item 15B</u>
6-301.11 Handwashing Cleanser, Availability
6-301.12 Hand Drying Provision</td></tr>
</table>

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1997 FOOD CODE

CDC Risk Factor OTHER Foreign Substance	CDC Risk Factor SUPPLEMENTAL ITEMS
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)*	**17. Proper Cooking Temperature (supplement to 4G – 2001 *Food Code*)** **Data Item 17A** 3-401.11(A)(1)* Raw Animal Foods (pork) **Data Item 17B** 3-401.11(A)(2)* Raw Animal Foods (ratites and injected meats) **18. Hot Hold (135° F.) (supplement to 8A – 2004 *Food Code)*** **Data Item 18A** 3-501.16(A)(1)* PHF, Hot and Cold Hold **19. Employee Health 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 **20. Treating Juice – 2001 *Food Code*** **Data Item 20A** 3-202.110 Juice Treated 3-404.11 Treating Juice **21. Cooling Raw Shell Eggs – 2001 *Food Code*** **Data Item 21A** 3-501.14(D)* Cooling **22. Cold Holding – Raw Shell Eggs – 2001 Food Code** **Data Item 22A** 3-501.16(B) Hot and Cold Holding

Food and Drug Administration, Division of Cooperative Programs
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REFERENCE SHEET

CDC Risk Factor Supplemental Items	
23. Food & Food Preparation for Highly Susceptible Populations – 2001 *Food Code*	
Data Item 23A 3-801.11(A)(2)* Prohibited Foods	
Data Item 23B 3-801.11(B)* Prohibited Foods 3-801.11(E)* Prohibited Foods	
Data Item 23C 3-801.11(D)* Prohibited Foods	

LEGEND

C = Celsius
F = Fahrenheit
RTE = Ready-to-Eat
PHF = Potentially Hazardous Food
R.A. = Regulatory Authority

Annex VII – Baseline Comparability

HOW TO MAKE YOUR RETAIL BASELINE BE COMPARE-ABLE And Other Statistical Topics

Advice for state and local retail food safety officials by
Wallace E. (Bing) Garthright, Ph.D.,
Deputy Director, Division of Mathematics
FDA/CFSAN/Office of Scientific Analysis and Support

Many of you state and local government officials have expressed a desire to conduct baseline measurements of the occurrence of foodborne disease risk factors. Such measurements can be made with respect to FDA's Food Code and with respect to your own local codes. The best written guidance that you will find is the "Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors", published by the FDA on 8/10/2000. You can get the best personal guidance on the methodology from FDA's regional retail food specialists. The most important determinant of the quality of your baseline measurements will be the expertise of you and your people. I am a statistician, and I don't have the qualifications to conduct a baseline inspection.

A baseline measurement represents an investment of your time, and the following advice is intended to help you get some extra value back from your investment. In addition to all the immediate, local uses for your baseline measurements, most of you will want to compare baselines across jurisdictions and also with FDA's national baselines. This comparability will also be a big contribution to national efforts to improve food safety. This paper will describe several important principles that will give you the comparability that you want.

Purposes and scope of your baselines and FDA's baselines

FDA actually produced 9 baselines, 1 each for 9 different facility types. Three types were institutional: hospitals, nursing homes, and elementary schools. Two types were restaurants: fast food and full service. And four types were departments of a retail food store and types of specialty stores: deli, meat-and-poultry, produce with and without salad bars, and seafood.

For each baseline, for example for hospitals, we combined scores for 42 individual items. These were grouped into 6 groups corresponding to CDC's risk categories:

- food from unsafe sources,
- improper holding temperatures,
- spread of microbes from foodworkers to the food,
- contaminated equipment,
- improper cooking, and
- improper control of chemicals.

At each inspection, each of the 42 items was given one of four scores:

- If the item didn't apply to the operation, is was scored "NA" for "not applicable" (e.g., proper cooking doesn't apply to the produce department).
- If the item did apply but couldn't be observed, it was scored "NO", for "not observed" (e.g., cool-down was begun but not completed during the inspection).
- If the item was adequately observed, it was scored either "IN" or "OUT" of compliance with the Food Code.

There were two purposes for FDA's 9 baselines. First, we wanted to know what were the most urgent priorities for improvement. Second, we wanted to make a measurement that we could repeat in 5 years to see what changes had occurred.

These were valuable purposes, and we believe we achieved them, but there was another purpose that we lacked the resources to achieve: a precise estimate of national conditions. Our baseline does give a crude estimate of the actual rates of occurrence across the U.S., but our sample was too small and too non-randomly selected to give as much accuracy as we would have liked for a national estimate. We simply didn't have the resources to do better. Many states and localities, however, have the resources to get more precise and more representative estimates, and that will lead to different purposes for carrying out the data collection.

Your agency might not have responsibility for all 9 facility types in FDA's baselines. That's no problem. You can pick as few as one facility type to make a baseline measurement and it will have value for you. It can still be compared with FDA and with other local baselines on that same facility type. You might also want to add new facility types such as day care or catering.

You might want your local baseline to have additional purposes. Because you have fairly complete inventory information, often by risk categories, and because you visit the establishments in some regular pattern,

- you might be able to get accurate measurements of occurrence rates;

- you might also want to expand the list of items, adding ones of special local interest (e.g.: additional local code items; emphases on special types of foods);
- you will probably want to compare your baseline with FDA's and with neighboring jurisdictions.

How to achieve comparability with FDA and other baselines—three principles

I know from experience that you will want to make lots of comparisons with FDA's baseline, with other jurisdictions, and with your own data over several years' time. You can expand the items scored or the set of facility types and still compare your results with FDA and with other localities, provided you follow three principles. Let's look at these principles one at a time.

The first principle is "Don't delete, alter, or merge any of the 42 risk-related items."

There is always pressure to make data collection forms shorter and to reduce data elements to their minimum, and this pressure motivates folks to see if they could live without an item or two. It will be especially tempting to delete an item that doesn't fit your local code, say when your local temperature requirements are different from the Food Code. It does take some extra effort to record compliance with items that are not in your local code, but if you remove the Food Code items, you'll lose comparability. You can always add your local items by expanding the set of data items. Then for comparison purposes you can use the FDA subset of 42 items.

You might have a locally important item that you want to incorporate, and it might look efficient to alter a baseline item by adding "or requirement X". If you do this, then you won't be able to tell why the merged item was found out of compliance—it could have been due to the original question or it might have been due to the part you added—or both. Now you won't be able to compare your results for that altered item.

There are similar reasons that you should not merge, nor combine, any of the 42 risk items in the current baseline with each other. Merging risk items will usually change the overall compliance rate and the specific risk category rate, sometimes in opposite directions! It is almost certain to create some distortions.

Let me give an actual example of such merging of items. One draft local form that I have seen does some merging of FDA's items under the risk factor "Pathogen Destruction". The draft local form combines 8 FDA cooking temperature items into one overall cooking temperature item. It also combines FDA's 4 rapid reheating for hot holding items into another single item.

Suppose we inspect Joe's Diner, using both FDA's form and the local form. Also suppose that we are able to observe all 12 of these items in action. Suppose Joe's Diner is In Compliance with 11 items but OUT of compliance on one item.

- FDA would find Joe's Diner to be out of compliance on one of the 12 items and in compliance on the remaining 11 items. Therefore FDA would say that Joe's is 8 percent out of compliance for pathogen destruction.
- The local baseline would find Joe's Diner out of compliance on one of 2 items and in compliance on the other item. Therefore the local form would say that Joe's is 50 percent out of compliance for pathogen destruction.

Fifty percent is a lot different from 8 percent, yet both forms are correctly tabulated. They just don't give statistics that we can compare.

In general, when you merge items from the FDA baseline to reduce the complexity of your local form, you make your inventory look more out of compliance for whatever risk factor is involved.

It's not clear that you will want to compute any overall compliance scores, since the risk factor scores are really more informative. For presentation to some audiences, however, you might be forced to use just the overall compliance score. In this case, the mergers in the pathogen destruction factor from 12 items to 2 items will reduce the importance of pathogen destruction 6-fold. Now pathogen destruction will contribute only 2 items to the overall compliance score, instead of 12. Now the overall score is really measuring something very different from the FDA overall score, and from many other local summaries, so no comparison is possible.

I gave this genuine example of merging 12 items into two, and it's obvious that such a big change would distort the local baseline. When we merge just two items into one, the distortions are weaker, but they are just as real. To avoid distortions, don't merge items.

The second principle is "Don't merge any facility types."

There are two types of facility mergers that could distort your baseline. In the first type, you might be tempted to merge two grocery store departments and treat them like a single department. For example, if you merge the meat & poultry department with the seafood department, you would have a single meat, poultry, and seafood department. This has an understandable meaning, but the compliance rate of this merged department would often be lower than the compliance rates of either the seafood department or the meat & poultry department. For example, if an item were out of compliance in seafood but in compliance for meat & poultry, we would lose the information that the meat & poultry operation was in compliance. This fact would be overridden by the "OUT"

score in seafood. A combined store department would always receive the worse of the two individual ratings.

Another way to merge facility types would be to combine two sets of establishments into one more general set. It might be tempting to merge fast food with full service. But consider how this could affect two counties, call them Jones County and Smith County.

In each county, fast food is 85% compliant and full service is 65% compliant. But suppose that 2/3 of the restaurants in Jones County are full service and only 1/3 of the restaurants in Smith County are full service. The result will be:

- Jones County has 72% IC (85% fast, 65% full)
- Smith County has 78% IC (85% fast, 65% full)

Clearly, both counties' programs as equally effective, but Smith looks 6 percentage points better than Jones. How many years do you think Jones county will be badgered to improve and catch up to Smith County? And they're already equal!

To avoid this sort of distortion, and to be comparable to FDA's baselines, don't merge facility types.

<u>The final principle is to retain the two codes for "not applicable" and "not observed".</u>

Most people are familiar with the use of the "not applicable" code, and most are easily persuaded to use it. The "not observed" code is much more uncommon, and will not be appreciated unless you insure that it is appreciated. There are only a few items for which the "not observed" will never apply. For example, you could not fail to observe stationary installed items like handwashing sinks and the soaps, etc. available there. A restaurant that serves shellfish only in a different season of the year, however, would be "not observed" if you visit them in the non-shellfish season. A temperature time relationship that begins when a restaurant closes at 2:00 a.m. and continues for four hours of cooling might not always be practical to observe. Another correct "not observed" situation.

If you drop the "NO" finding from an item to which it could apply, then you will be coding such items "IN" compliance when you can't observe them, because they were not observed to be out of compliance. <u>In this situation, you no longer know what your "IN" compliance rates really mean.</u> Without knowing that your in-compliance findings are based on observations, you cannot present them as positive findings of good operations. You don't want to perform all this work and have your results reduced in value. Keep NA and NO as permissible codes for almost all items.

To summarize the principles that let you compare your results,

- Preserve the 42 risk-related items as they are, adding separate items where you wish.
- Don't merge facility types with each other or with new ones.
- Preserve both codes for "not applicable" and "not observed."

How to Get Full Feedback About Needed Revisions to Your Instruction Set

No set of data collection forms or marking instructions will suit all situations or remain current without revisions. You know, better than I do, how rapidly your retail food technologies and market structures are changing. This means that a baseline inspection will often encounter new situations for which the current instructions are not clear. You will need frank feedback from your investigators, and that presents a big problem. Many of our best people are proud of their initiative and ability to overcome obstacles. They don't want to ask for help, but rather want to show that they can make independent decisions. Therefore, when it's not clear how to score an item at a particular establishment, they will make a good judgment and just do it. The problem is that two good inspectors might make two different judgments, and when you get around to analyzing the in-compliance rate, you may find that the data are flawed and the marking instructions are not clear.

The self-reliant, sef-assured inspector will need a lot of encouragement from management before he or she will point out those instances where the marking instructions for individual data items are unclear or leave too much room for judgement. Your people need to trust that, when they send you extra feedback about scientific data collection instructions that don't seem to fit a situation, you will receive it openly and give consideration to each suggestion.

It's in those gray areas, where decisions are hard, that you will discover the changes in food processes that will require new baseline instructions. Your compliance people are now collecting scientific data, and this requires less self-reliance and more concern for consistency. It will require superb leadership to get their full participation in a continuing, scientific critique of the data collection methods.

Naturally, your FDA regional specialist will be appreciate being told about any difficulties you encounter and will share with the whole FDA team your ideas for improvements and adaptations to new requirements.

Annex VIII – FDA Regional Food Specialist Listing

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