

EHS-Net Food Safety Practices & Beliefs Study

EHS-NET Generic Information Collection Request

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Supporting Statement - B

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Program Official:

Adam Kramer Sc.D., M.P.H., R.S.

Environmental Health Officer

Centers for Disease Control and Prevention

National Center for Environmental Health

Emergency and Environmental Health Services

Environmental Health Services Branch

4770 Buford Highway, NE F – 58

Atlanta, GA 30341-3724

404-498-1228 (Phone)

770-488-3635 (Fax)

E-mail: ank5@cdc.gov

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

EHS-Net is a collaborative project of the CDC, FDA, USDA, and eight state and local public health departments (California; Minnesota; New York City; New York State; Rhode Island; Tennessee; Southern Nevada Health District, NV; and Harris County, TX.) The respondent universe is comprised of retail food establishments in selected geographical areas within the EHS-Net catchment areas. While the number of areas included in EHS-Net is small, they are demographically diverse and provide good geographical coverage of the U.S. (northeast, mid-west, south, and west). When the sampling methods outlined here for ensuring a representative sample in the current study are used, the results of the collection covered by this PRA clearance can be used to generalize only to the population of retail food establishments in the given EHS-Net site(s).

The respondent universe is all retail food establishments (hereafter referred to as restaurants) in the EHS-Net catchment area. Restaurant lists will be obtained from the restaurant databases maintained by the EHS-Net sites. CDC will use these restaurant lists to generate the sampling frame used to draw the sample for this study.

Each EHS-Net site will enroll 47 restaurants in the study (Table B.1). Since there are no previously published (population) studies that have examined food safety culture in conjunction with organizational practices in restaurants, we are unable to determine whether this sample size will be able to support at least an 80% study power to detect statistical differences between study groups. Thus, data on expected prevalence of knowledge, attitudes, and practices between different groups of restaurants are not available as inputs for proper calculation of study sample size and power. Enrollment of 47 restaurants per EHS-Net site, totaling 376 restaurants for the entire study, is a reasonable sample size and follows the precedent of previous EHS-Net studies (Green et al., 2006; Kirkland et al., 2009; Sumner et al., 2011). Experience from prior EHS-Net studies also indicates that a sample size of 376 should be sufficient for the analytic purposes outlined below, since the analytic parameters are not likely to be considered rare (in distribution) events. Data collected from this study will provide the necessary information for sample size and power calculations for future studies.

Table B.1

Strata (EHS-Net Sites)	Entity	Number of Entities
California	Restaurants	47
Minnesota	Restaurants	47
New York	Restaurants	47
New York City	Restaurants	47
Rhode Island	Restaurants	47
Tennessee	Restaurants	47
Southern Nevada Health District	Restaurants	47
Harris County, Texas	Restaurants	47

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The design is cross-sectional and uses a stratified random sampling plan in which each EHS-Net site serves as its own mutually exclusive stratum. There are two primary reasons for stratifying by EHS-Net site. The first is that food safety regulations vary by jurisdiction. For example, Tennessee state food safety regulations differ from New York state food safety regulations. These regulations can and do greatly influence restaurants' food safety practices and procedures. EHS-Net site/jurisdiction, therefore, poses the largest source of variability from a study design perspective. Thus, it is a critically important factor for stratification. The second reason for stratifying by EHS-Net site only is due to practical concerns that limit our ability to stratify on other variables of interest. EHS-Net sites participate in EHS-Net through a cooperative agreement. See Table B.2 for EHS-Net sites' cooperative agreement numbers. The nature of this agreement is such that one site cannot be expected to do a disproportionate amount of work in comparison to other sites (because each site receives relatively equal funding amounts). If we did not stratify by EHS-Net site but by some other factor such as ownership (independently owned or belonging to a corporate chain), it is likely that some sites would have to carry a greater burden than other sites in term of recruiting and collecting data in a larger number of restaurants. However, we will be collecting data on these factors of interest and will account for their heterogeneity through statistical modeling. Finally, the need for each site to share an equal burden in data collection is the reason why a fixed-sample allocation method was used for each site (47 establishments per site), instead of a proportionate-sample allocation.

Table B.2

EHS-Net Sites	CDC-NCEH Cooperative Agreement Numbers
California	EH001299
Minnesota	EH001295
New York	EH001296
New York City	EH001300
Rhode Island	EH001293
Tennessee	EH001294
Southern Nevada Health District	EH001301
Harris County, Texas	EH001297

Restaurants will be randomly selected, with equal probability, within their respective EHS-Net site, independent of other sites. This process will give each restaurant in a particular sampling frame the same probability of being selected for study participation. There are three reasons for employing this sampling strategy: reducing sampling error, maintaining equal representation by site, and ensuring generalizability. First, as stated previously, the total target population of restaurants from all EHS-Net sites combined constitutes a highly heterogeneous group. To control for such heterogeneity in the total sample, restaurants will be stratified by EHS-Net site so they can be grouped into more homogeneous strata and then sampled within stratum independently. This reduction in heterogeneity of the total sample will lead to a reduction in sampling error, which can improve representativeness of the selected sample and provide estimates (e.g., means) that tend to have less variability than estimates produced from samples that were drawn using the un-stratified, simple random sampling method. Second, with equal allocation of samples (47 restaurants per site), each EHS-Net site will have equal representation

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in the parameter estimates of the combined sample. An additional benefit is that even sites with small sampling frames will have sufficient data points to support their site-specific analyses. Third, by ensuring that the sampling of restaurants is done by an entity (CDC) separate from the data collectors (EHS-Net sites) and employing a random selection method, we are able to minimize the potential for selection bias. Parameter estimates or study findings obtained from an unbiased study sample could be generalized to the entire EHS-Net target population.

The average response rate across EHS-Net studies that used methods similar to the proposed study is 45% (Brown et al., 2016; Brown et al., 2014; Radke et al., 2016). We expect a similar response rate for the proposed study.

2. Procedures for the Collection of Information

As indicated earlier, each EHS-Net site will provide CDC with a list of all restaurants in their catchment area. This list will serve as the sampling frame for the site. CDC will use a random number generator in SAS 9.3 to produce a random sample of restaurants from this restaurant list for each site. As we expect some restaurants will refuse to participate and some will be ineligible to participate, we will select more than the needed number of restaurants--100 restaurants for each site. Once they receive their sample list from CDC, personnel in each site will contact restaurants by telephone to recruit their participation in the study. If the manager is willing to participate, the EHS-Net specialist will arrange a mutually convenient time to conduct the data collection.

In instances where an EHS-Net site is unable to recruit 47 restaurants from the first list of 100 restaurants, CDC will randomly select another group of 47 restaurants for the site to use to recruit additional respondents. Recruitment will be considered complete once data are collected in 47 restaurants. EHS-Net sites will recruit via the telephone and will keep a log of each contact with the restaurants to document participation rates and reasons for refusal and/or ineligibility.

CDC will not know which restaurants on the sample lists participated in the study, and thus will not be able to link restaurant names with any study data. The restaurant identifying information will be maintained by the respective EHS-Net site to facilitate the site visit, but will be destroyed when it is no longer needed. Additionally, on all forms only the specific coded restaurant identifier will be used to minimize a risk of someone inadvertently seeing a completed form and being able to associate it with a specific restaurant.

Data will be collected in the restaurants by the EHS-Net environmental health specialists. For the manager interview portion of the study, the EHS-Net specialist will obtain verbal informed consent and then conduct a face-to-face interview with a manager who has authority over the kitchen and can speak English well enough to complete the interview in English. This interview will include questions on restaurant characteristics, procedures, and food safety-related practices (Attachment 5). This will take about twenty minutes to complete.

For the worker survey portion of the study, the data collector will obtain verbal informed consent from and then administer a written survey (Attachment 8). A flyer (Attachment 7) will be left with the restaurant with a link for other food workers to take an electronic version of the same

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survey at their convenience (Attachment 9). The survey includes questions on employee beliefs, food safety knowledge, food safety related practices, and worker demographics. The survey will be administered to all workers that handle food and voluntarily agree to participate. The survey will be administered in English.

For the restaurant environment observation (Attachment 10) portion, the data collector will observe the kitchen and note the food-safety related infrastructure and the implementation of specific food safety practices.

The data collectors are experienced and knowledgeable in environmental health and food safety and will have received training from CDC on data collection for this study. The EHS-Net administrator in each EHS-Net site and CDC staff will perform quality assurance procedures to check for data entry errors.

Managers' concerns about the safety practices of their restaurants may result in selection bias- a lower rate of study participation among restaurants with worse or non-existent safety practices compared to restaurants with better safety practices. We have conducted studies using methods similar to those proposed for use in this study in the past, and these studies have found a wide range of food safety practices, including poor ones (Bogard, Fuller, Radke, Selman, & Smith, 2013; Brown, Khargonekar, & Bushnell, 2013; Brown et al., 2012; Coleman, Delea, Everstine, Reimann, & Ripley, 2013; Green et al., 2006; Kirkland et al., 2009; Lee et al., 2004; Sumner et al., 2011). While the potential for selection bias exists, these studies indicate that these biases may be minimal. Plus, the study protocol incorporates procedures to minimize the potential for and to detect any indication of selection bias. For example, EHS-Net staff will be trained in the recruitment process in order to keep non-response rate as low as possible, which will help minimize selection bias.

The interview and survey data collected for this study may be influenced by social desirability bias- the tendency for people to report greater levels of socially desirable behavior (such as not working while ill) than they actually engage in, or to report their best behavior rather than their typical or worst behavior. Although it is difficult to eliminate this bias altogether, it can be limited by ensuring respondents that the information they report will be anonymous, which we will do (Leary, 2004).

Due to logistical limitations, we will only interview managers that speak English well enough to be interviewed, and provide a written survey to workers in English. The food workers will need to have sufficient literacy to read English. The use of this criterion may introduce bias, as less literate individuals may have different food safety knowledge, attitudes and practices than more literate workers, but the resources are not available to include non-English speaking staff in the study or translate all of the documents into the potential universe of languages spoken in restaurants.

Any presentation of data from this study will acknowledge these potential biases and include a discussion of how they impact data interpretation.

3. Methods to Maximize Response Rates and Deal with Nonresponse

We will engage in several activities designed to maximize response rates. First, all recruiters will receive training on the recruiting process that will be locally developed by EHS-Net sites. Second, multiple attempts will be made to contact potential respondents. Specifically, recruiters will make 10 attempts over 5 days to get a participation response from establishments they have not been able to contact, and 5 attempts over 5 days to get a participation response from restaurants that have not provided a response (e.g., ‘call back later’). Third, recruiting scripts will emphasize two issues that have been shown to increase response rates—the anonymous nature of the data collection and the importance of the respondents’ participation in the study.

4. Test of Procedures or Methods to be Undertaken

The data collection materials and methods are based on those used in other previous, successful EHS-Net studies (Bogard et al., 2013; Brown et al., 2013; Brown et al., 2012; Coleman et al., 2013; Green et al., 2006; Kirkland et al., 2009; Lee et al., 2004; Sumner et al., 2011). All data collection materials were reviewed and evaluated by key EHS-Net specialists whom are experienced with collecting data for EHS-Net studies. They were also reviewed by CDC EHS-Net personnel with extensive experience in developing and conducting EHS-Net studies. Additionally, all data collection materials were evaluated in pilot tests with 9 retail food establishments. Given that we are experienced in collecting data from retail food establishments with these types of instruments and methods (this will be the tenth multisite study we have conducted in retail food establishments using similar data collection instruments and methods), we are confident that the study is designed well and do not anticipate the need to make changes to the data collection instruments. An initial pilot study was done with two restaurant workers to verify the length of time and the survey questions and we do not anticipate any changes, are needed to the data collection instrument,

Data Analysis Plan. The primary purpose of this data collection is to examine the extent of the employee’s food safety culture (food safety beliefs), organizational procedures, and implementation of food safety practices (including implementation of the date-marking and consumer advisory provisions of the Food Code) to understand the interconnection of beliefs, procedures, and practices to allow for enhanced intervention development in the future. To address the purposes of this data collection, we will conduct descriptive analyses (frequencies, means, etc.) along with a factor analysis to identify the domain areas that the belief statements are attached to (Table B.4.2 – Attitudes - contains hypothesized domain areas based upon the literature). Tables B.4.1-4.2 contain the variables included in these analyses. Table B.4.3 contains variables used to describe the restaurant, along with the managers and food workers. Table B.4.4 is a table shell that illustrates how we may analyze and present the descriptive data collected from this study.

Table B.4.1 Variables measuring organizational practices

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<i>Item Content</i>	MI#	FWS#	OBS#
Existing Food Safety Practices			
Implementation of consumer advisory provisions	31-32	37-38	11-12
Implementation of date-marking provisions	33		14
Implementation of cold-holding requirements			15
Implementation of bare hand contact restrictions	25		23
Hand sink availability and functioning			24
Implementation of handwashing practices			25
Organizational Practices			
Use of logs, check sheets, and job aids			16-21
Employee training	27-30		
Development of food safety procedures	26		
Incentivizing food safety performance	6		

MI = Manager Interview, FWS = Food Worker Survey, OBS = Restaurant Observation Form

Table B.4.2 Variables measuring knowledge and attitudes

<i>Item Content</i>	FWS#
Knowledge	
Our restaurant cooks and then cools down a meat product (such as chicken) for later service on March 15. When must it be used by	39
Hands should be washed prior to handling food, plates or utensils after (check all that apply)	41
Cold held meats or other refrigerated items should be kept at _____ or below	42
Hot held meats or other hot items should be kept at _____ or higher	43
What symptom(s) are most likely to indicate an employee has an illness that can be spread through food	44
What is the proper procedure for washing your hands	45
Food that is cooked and then cooled must be cooled down within the following timeframe	46
The proper order for dishwashing (either manually in a three-compartment sink or using a dishwasher) is (pick one)	47
Attitudes	
Leadership	15,16,18,19,20,22
Communication	17,25,26,28,29
Commitment	2-5,24,27
Resources	8-14
Risk awareness	6,7,21,23,30,31-36

FWS = Food Worker Survey

We will also need to describe the restaurants, managers, and workers from which we collect the data. Table B.4.3 contains the variables needed for these analyses.

Table B.4.3 Variables measuring restaurant and individual characteristics

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<i>Item Content</i>	MI#	FWS#	OBS#
Restaurant Characteristics			
Is this restaurant independently owned or part of a local, regional, or national chain	7		
Which of the following options best describes the restaurant style (Family style, Fast casual, Fast food, Fine dining, Buffet, Café/Bistro)	8		
What is the seating capacity of the restaurant	9		
Employee tenure	14-16		
Certified Food Protection Manager Present	22-24		
Level of food handling			8
Individual Characteristics			
Years of experience	1	48	
Training	2-3	49-51	
Level of education		55-56	

MI = Manager Interview, FWS = Food Worker Survey, OBS = Restaurant Observation Form

Table B.4.4- Table Shell: Descriptive data on Organizational practices

	n	%
Restaurant has food safety procedures (MI26)		
Written	XX	XX
Verbal	XX	XX
Combined written and verbal	XX	XX
No food safety-related procedures	XX	XX
Compliance with food safety requirements		
Handwashing (OBS25)	XX	XX
Cold holding (OBS15)	XX	XX
Bare hand contact restrictions (OBS23)	XX	XX
Date-marking of Ready to eat foods (OBS14)	XX	XX
Consumer Advisory for raw or undercooked foods (OBS11-12)	XX	XX
Use of Logs, Check-sheets or Job-aids (OBS16-21)		
Yes	XX	XX
No	XX	XX
	Mean	SD
Employee knowledge (FWS39-47)	XX	XX
Food Safety Culture Index	XX	XX
Leadership (FWS15,16,18-20,22)	XX	XX
Communication (FWS17,25-26,28-29)	XX	XX
Commitment (FWS2-5,24,27)	XX	XX
Resources (FWS8-14)	XX	XX
Risk Awareness (FWS6-7,21,23,30-36)	XX	XX

MI = Manager Interview, FWS = Food Worker Survey, OBS = Restaurant Observation Form

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The primary purpose of this study is understanding the environmental factors within a restaurant that may be an underlying cause of foodborne illness through examining the inter-relationship of employee beliefs and knowledge with organizational practices and a restaurants implementation of safe food handling practices (including implementation of the date-marking and consumer advisory provisions of the Food Code.) To address this purpose, a multivariable regression model will be used to model the percentage of in compliance food safety practices against the percentage of food safety questions answered correctly and the food safety culture index. The food safety culture index will be developed using factor analysis on the belief statements from the food worker survey. Hypothetically there may be five domain areas based upon the literature (Leadership, Communication, Commitment, Resources, and Risk Awareness). If a statistically significant model is detected, we will conduct further tests of association with regression models with both individual and restaurant characteristics. Analysis will involve bivariate tests for association between each individual explanatory (independent) variable and the outcome (or dependent) variable of interest (food safety performance, knowledge, and beliefs.) Odds ratios will be calculated to assess the strength and direction of the bivariate relationships. For those bivariate associations found to be statistically significant at $p < .30$, the explanatory variables will be used as candidate “predictors” to examine their multivariate relationships with the outcome variables. Multivariable regression will be used to model for the effects that these explanatory variables have in explaining the variations observed in the outcome variables. The increased number of food worker surveys will allow us to potentially do cluster analysis within a restaurant, providing evidence of the effects within a restaurant in addition to between restaurants.

Explanatory variables in these analyses include those measuring restaurant and staff characteristics. Outcome variables include those measuring food safety practices, employee food safety beliefs, and food safety knowledge. However, analyses will focus on *key practices*. Table B.4.5 lists the key explanatory variables and key practice outcome variables based on the individual variables listed in the table. Table B.4.6 is a table shell that illustrates how we might analyze and present the data examining the relationships between restaurant and staff characteristics and key practices.

Table B.4.5- Key explanatory and practice outcome variables included in explanatory analyses

Explanatory variables	Outcome variables
<p><i>Restaurant characteristics</i></p> <ul style="list-style-type: none"> • Industry segment (MI8) • Volume of business (MI11-13) • Turnover of staff (MI14-16) • Certified kitchen manager present (MI22-24) • Level of foodhandling (OBS10) <p><i>Employee characteristics</i></p> <ul style="list-style-type: none"> • Years of experience (MI1,5, FWS48,52) • Food safety training (MI3, FWS49-51) • Position in restaurant (MI4, FWS53) 	<ul style="list-style-type: none"> • Food Safety Culture Index (comprised from the hypothesized constructs below) <ul style="list-style-type: none"> ○ Leadership (FWS15,16,18-20,22) ○ Communication (FWS17,25-26,28-29) ○ Commitment (FWS2-5,24,27) ○ Resources (FWS8-14)

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	<ul style="list-style-type: none">o Risk Awareness (FWS6-7,21,23,30-36)• Compliance with food safety requirements (OBS11-12,14-15,23,25)• Food safety knowledge (FWS39-47)
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MI = Manager Interview, FWS = Food Worker Survey, OBS = Restaurant Observation Form

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Table B.4.6- Table Shell: Key restaurant and manager characteristic explanatory variables associated with the practice outcome variables, bivariate analyses

Explanatory variables	Compliance with Food Safety Requirements (OBS: 11-12,14-15,23,25)	
	OR (95% CI)	P
<i>Restaurant characteristics</i>		
Volume of business (MI11-13)		
≥ xxx	x.xx (ref)	.xxx
< xxx	x.xx	
Turnover of staff (MI14-16)		
≥ xx	x.xx (ref)	.xxx
< xx	x.xx	
Certified kitchen Manager (MI22-24)		
Some hours	x.xx (ref)	.xxx
All hours	x.xx	
Not present	x.xx	
Industry Segment (MI8)		
Fast food	x.xx (ref)	.xxx
Fast casual	x.xx	
Fine dining	x.xx	
Family style	x.xx	
Buffet	x.xx	
Other	x.xx	
Level of foodhandling (OBS10)		
Prep-Serve	x.xx (ref)	.xxx
Cook-Serve	x.xx	
Complex	x.xx	
<i>Employee characteristics</i>		
Employee experience (MI1,5, FWS48,52)		
≥ xx years	x.xx (ref)	.xxx
< xx years	x.xx	
Employee certified (MI3, FWS49-51)		
Yes	x.xx (ref)	.xxx
No	x.xx	
Position in restaurant (MI4, FWS53)		
Manager	x.xx (ref)	.xxx
Cook	x.xx	
Food preparation	x.xx	
Other	x.xx	

OR=Odds Ratio, P=probability level, MI = Manager Interview, FWS = Food Worker Survey, OBS = Restaurant Observation Form

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5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following people were primarily responsible for the design, including the statistical aspects, of the data collection and will be primarily responsible for data analysis. Laura Brown is the primary contact for statistical aspects and data collection.

Laura Green Brown, Ph.D.

Behavioral Scientist
Centers for Disease Control and Prevention, National Center for Environmental Health
Lrg0@cdc.gov
770-488-4332

Adam Kramer, Sc.D., M.P.H, R.S.

Environmental Health Officer
Centers for Disease Control and Prevention, National Center for Environmental Health
Ank5@cdc.gov
404-498-1228

Rick Hoover, Ph.D.

Behavioral Scientist
Centers for Disease Control and Prevention, National Center for Environmental Health
Xmo2@cdc.gov
706-765-8857

Personnel in the eight EHS-Net sites will be responsible for data collection (See table below). In some cases, environmental health specialists from non-EHS-Net sites assist with data collection; these personnel are not included in this table.

Site	Number of Personnel
California Department of Health	1 full-time
Minnesota Department of Health	1 full-time 1 part-time
New York Department of Health	1 full-time 1 part-time
New York City Department of Health and Mental Hygiene	1 full-time
Rhode Island Department of Health	1 full-time
Tennessee Department of Health	1 full-time 1 part-time
Southern Nevada Health District	1 full-time
Harris County, Texas	1 full-time

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References for Part B

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