Supporting Statement B

National Environmental Assessment Reporting System (NEARS)

(formerly National Voluntary Environmental Assessment Information System [NVEAIS])

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REVISION

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B. Collection of Information Employing Statistical Methods

Statistical methods will not be used to select respondents for this data collection. All food safety programs in the United States will be invited to participate; however, participation is voluntary. Programs that participate in NEARS will report data on all outbreaks occurring in their jurisdictions. We expect that program participation will increase over time. However, until all eligible programs are participating, a limitation of our data will be that it applies to only those jurisdictions participating in NEARS. We will use this section of the supporting statement to describe data collection procedures.

B.1. Respondent Universe and Sampling Methods

State, local, tribal, and territorial food safety programs will report data into NEARS. There are approximately 3,000 such food safety programs in the United States.

Although the data reported through this system are collected *by* food safety programs; they are not collected *on* food safety programs or personnel. Instead, they are collected primarily on foodborne illness outbreaks. Specifically, data collected by food safety programs during their investigation of foodborne illness outbreaks will be reported into NEARS. These data will provide information on environmental factors associated with outbreaks.

Data on all outbreaks occurring in the jurisdictions of participating food safety programs (the NEARS 'catchment area') will be reported to NEARS. Thus, we will be utilizing a convenience sample of voluntary participating programs and not obtaining a statistical sample. In the future, should a nationally representative program evolve, we may be able to generalize our data. Currently, we will describe the population of outbreaks solely in the NEARS catchment area and the environmental factors associated with them, and not generalize the data as nationally representative.

B.2. Procedures for the Collection of Information

Data Collection

Prior to collecting data, all food safety program personnel participating in NEARS will be encouraged to attend training for NEARS. These staff will be encouraged to attend a Lync Meeting (i.e., webinar) training session conducted by CDC staff (Attachment 4). This training is voluntary and will cover identifying environmental factors, logging in and entering data into the web-based NEARS data entry system, and troubleshooting problems. There will be no website, form, or presentation document associated with this training. Instead, CDC personnel will be guiding participants through the NEARS data entry system. Attachment 4 contains a brief description of the training.

Although not a requirement food safety program personnel participating in NEARS will also be encouraged to complete CDC's e-Learning on Environmental Assessment of Foodborne Illness Outbreaks (Attachment 5). This e-Learning course provides training on how to use a systems approach in foodborne illness outbreak environmental assessments. Participants acquire in-depth skills and knowledge to investigate foodborne illness outbreaks as a member of a larger outbreak response team, identify an outbreak's environmental causes, and recommend appropriate control measures. The course is presented in the context of a simulated virtual environment where participants can interact and practice the skills being learned. Attachment 5 contains a brief description of the training.

There are two data collection activities. For the first activity, participating food safety programs will record all their environmental assessment data by pen-and -paper form (Attachment 6) and then enter all their data into the secure NEARS web-based system (Attachment 7), which is designed to make data entry easy for respondents. The respondents for this activity are the food safety program personnel participating in NEARS. This will be done once for each outbreak.

The second activity is the manager interview that will be conducted at each establishment associated with an outbreak (Attachment 8). The respondents for this activity are the retail food managers of the outbreak establishments. Manager interviews are a routine part of outbreak investigations; however, food safety program personnel participating in NEARS conducts a structured interview, and will thus conduct their interviews slightly differently than they would if they were not participating in NEARS.

Data analysis results will be shared informally with participating sites through annual data summary reports and presentations during NEARS quarterly webinars. Results will also be shared with other stakeholders (e.g. NORS Team) and the food safety and environmental public health community through presentations at meetings and conferences, peer-reviewed publications in scientific journals, and possibly 'plain language' summaries on the CDC website. Results will be presented in aggregate form.

The results will be used to develop recommendations for food safety and environmental public health programs and the retail food industry. For example, if data collection identifies specific environmental antecedents are associated with certain foodborne outbreaks, CDC can develop recommendations that address these unsafe polices and/or practices and disseminate the information to environmental public health programs and the retail food industry.

Quality Control Procedures

CDC personnel will periodically review the data from each site, and perform quality assurance procedures to check for data entry errors. They will provide reports to each program about the quality of their data. CDC personnel will use these reports to highlight weaknesses in data and recommend ways to improve the quality of the data.

Potential Biases

The act of observing workers during environmental assessments may influence their performance and behavior on work-related tasks. In other words, the workers may not respond naturally when they know they are being observed. However, for the most part, those collecting these data will be experienced and will take measures (such as remaining unobtrusive and engaging in activities that will place workers more at ease) to minimize this bias when possible.

The manager interview data may be influenced by social desirability bias - the tendency for people to report greater levels of socially desirable behavior (such as safe food preparation practices) than they actually engage in, or to report their best behavior rather than their typical or worst behavior.

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

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

Program Response

We have been and will continue to engage in activities to promote and encourage food safety program participation in NEARS. We have presented at multiple conferences attended by those responsible for outbreak investigation (e.g., National Environmental Health Association, Council to Improve Foodborne Outbreak Response etc.). We will hold informational conference calls with programs interested in NEARS. During these calls, we will attempt to identify barriers to NEARS participation and address those barriers. Our goal is to achieve close to 100% participation in NEARS.

B.4. Test of Procedures or Methods to be Undertaken

The data collection instrument to be used for the NEARS was previously developed by the Environmental Health Specialists Network (EHS-Net) (See Attachments 6, 7, and 8). As food safety programs beyond the EHS-Net participants continue using the instrument, we expect that they will identify some components of the instrument that need revision. We expect these revisions to be minor. We plan to annually review respondents' revision comments and questions to determine the nature and scope of requested revisions. Annual review of data may also reveal minor needed changes. Should we identify the need for changes to the data collection instruments, we will submit a nonmaterial or non-substantive change request to OMB for approval. For major changes to the instruments or methods, a full revision ICR will be submitted for Paperwork Reduction Act (PRA) clearance.

Data Analysis Plan

The three main goals of this data collection are to:

- 1. Describe foodborne illness outbreaks and outbreak responses.
- 2. Describe environmental factors (environmental antecedents and contributing factors) associated with outbreaks.
- 3. Describe the associations between environmental antecedents and contributing factors to outbreaks.

To address the first goal of this data collection, *describe outbreaks and outbreak responses*, we will conduct descriptive analyses (frequencies, means, etc.) to describe:

• outbreaks (Table B.4.1 contains the variables included in these descriptive analyses)

• outbreak responses (Table B.4.2 contains the variables included in these descriptive analyses).

Question		
Number	Question	Justification
I_1	Did the exposure(s) take place in a single or multiple locations, for example a single restaurant or two or more restaurants, a single school or two or more schools or a combination of establishments, etc.?	Describe whether single or multiple establishments were involved in the outbreak.
I_2	Did the exposure(s) happen in a single County/Township / Parish or multiple Counties / Townships / Parishes in your state?	Describe whether single or multiple jurisdictions were involved in the outbreak.
I_3	Did the exposure(s) occur in a single state or multiple states?	Describe whether single or multiple states were involved in the outbreak.
I_4	How many food service establishment locations within your jurisdiction were associated with this outbreak?	Describe how many food service establishments were associated with the outbreak.
I_5	Were any environmental assessments conducted at foodservice establishments in your jurisdiction as part of this outbreak	Describe whether environmental assessments were conducted.
I_5a	Briefly, describe the reason(s) why environmental assessments were conducted in your jurisdiction as a part of this outbreak?	Describe why and when environmental assessments were conducted.
I_5b	How many environmental assessments were conducted at foodservice establishments in your jurisdiction as part of this outbreak?	Describe how many environmental assessments where conducted in the reporting jurisdiction.
I_5c	Why were no environmental assessments conducted at foodservice establishments in your jurisdiction as part of this outbreak investigation	Describe why environmental assessments were not conducted.
I_6	Were any non-food service establishment locations within your jurisdiction were associated with this outbreak?	Describe whether any non-food service establishments were associated with the outbreak.
I_6a	How many non-food service establishment locations within your jurisdiction were associated with this outbreak?	Describe how many non-food service establishment locations were associated with the outbreak.
I_6b	How many environmental assessments were conducted at non-food service establishments in your jurisdiction as part of this outbreak?	Describe how many environmental assessments were conducted in non food service establishments.
I_7	Was a primary agent identified in this outbreak?	Describe the agent.
 I_7a	What was the identified agent? Was the identified agent suspect or confirmed?	
I_7b	Was a serotype identified in this outbreak?	Describe the serotype.
I_7c	What was the identified serotype?	
I_8	Was this outbreak reported to a state or local Communicable Disease Surveillance Program?	This information will be used to help connect the NEARS data to existing epidemiological and
I_8a	Select the state or local surveillance system(s) where this outbreak was reported.	laboratory data reported to the state.

 Table B.4.1. Variables included in descriptive analyses of outbreaks

I_9	Was this outbreak reported to a national	This information will be used to help connect the
	surveillance system?	NEARS data to existing epidemiological and
I_9a	Select the national surveillance system(s) where	laboratory data reported to other national
	this outbreak was reported and record the	surveillance systems.
	corresponding reporting number.	
V_1	Was a specific ingredient or multi-ingredient	Describe ingredients and foods associated with the
	food suspected or confirmed in this outbreak?	outbreak.
V_1a	If No, explain why food was the suspected	
	vehicle in this outbreak.	
V_2	Is this food a single specific ingredient or multi-	
	ingredient?	
V_3	What is the name of the suspected or confirmed	
	ingredient / food vehicle?	
V_4	Select the reason that best describes how this	Describes the type of information used to
	single specific ingredient or multi ingredient	determine the food associated with the outbreak.
	food was implicated in the outbreak.	
VI_3a	Where was the sample taken from?	Describe where environmental samples were
	-	taken.
VI_3	What type of sample was taken?	Describe if food sample is a single ingredient,
		multi ingredient food item or environmental.
VI_5	Was an agent identified in this sample?	Describe if an agent was found in sample.
VI_6	What was the identified agent?	Describe agent found in sample.
VI_6a	Was a serotype of the agent identified?	Describe if a serotype was found in sample.
VII_1	Were any contributing factors identified in this	Describe if contributing factors where identified in
	outbreak?	an outbreak investigation.

Question	Question	Justification
Number		
II_1	Date the establishment was identified for an environmental assessment	Describe how long it takes to respond to outbreaks with an environmental assessment.
II_2	Date of first contact with establishment management	
II_3	Number of visits to the establishment to complete this environmental assessment	Describe environmental assessment responses.
II_4	Number of contacts with the establishment other than visits, (ex. phone calls, phone interviews with staff, faxes, etc.) to complete this environmental assessment	
II_9	Was a translator needed to communicate with the kitchen manager during the environmental assessment?	Describe whether language and communication are issues in collecting information for environmental assessments.
II_9a	Was a translator used to communicate with the kitchen manager?	
II_10	Was a translator needed to communicate with the food workers during the environmental assessment?	
II_10a	Was a translator used to communicate with the food workers?	
III_1	Date the manager interview was conducted	Describe the time from identification/contact until
IV_1	Date observations were made	specific environmental assessment activities are conducted.
VI_1	Were any samples taken?	Describe how many samples and what type are

VI_2	How many samples were taken?	taken during environmental assessments.
VI_3	What type of sample was taken?	
VII_2	During the outbreak investigation, what activities were used to try to identify the contributing factors?	Describe outbreak responses.
VII_3	Please rate the quality of communication between the food regulatory program and the communicable disease control program during this outbreak investigation.	Describe outbreak responses.

To address the second goal of this data collection, *describe environmental factors associated with outbreaks*, we will conduct descriptive analyses (frequencies, means, etc.) to describe

- environmental antecedents (see Table B.4.3 for the variables included in these descriptive analyses and their environmental antecedent classifications [economics, equipment, food, people, processes])
- contributing factors (examined by category: contamination, proliferation, and survival; see Table B.4.4 for the variables included in these descriptive analyses).

The list and descriptions of all contributing factors can be found in Attachment 3.

NEARS collects data on a number of environmental antecedent variables. These variables were chosen for inclusion in NEARS because existing hypotheses, theories or data suggest that they may be related to food safety and/or foodborne illness outbreaks.

Question	Question	Justification	Classification
Number			
Part II: Es	stablishment description, categorization	on and menu review	
II_5	Facility type	Describe facility type.	Process
II_6	How many critical violations were noted during the last routine inspection?	Describe critical violations.	Equipment, People, Process
II_7	What is the establishment's source of potable water?	Describe water source.	Equipment
II_8	What is the establishment's sewage disposal method?	Describe sewage disposal method.	Equipment
II_11	Establishment Type	Describe establishment type.	Process
II_12	Do customers have direct access to unpackaged food such as a buffet line or salad bar in this establishment?	Describe customer access to unpackaged food.	People
II_13	Does the establishment serve raw or undercooked animal products (example, oysters or raw shell eggs) in any menu item?	Describe whether this food safety risk exists and whether customers are notified of this risk.	Food, Process
II_13a	Is a consumer advisory regarding the risk of consuming raw or undercooked animal products provided?		People
II_13b	Where is the consumer advisory located?		People

 Table B.4.3. Variables included in descriptive analyses of environmental antecedents

	(Check all that apply)		
II_14	Which one of the options below best describes the menu for this establishment?	Describe the establishment menu.	Food, Process
Part III:	Manager Interview		
III_2	Is this an independent establishment or a chain establishment?	Describe establishment ownership.	People, Process
III_3	Approximately how many meals are served here daily?	Describe volume of business.	Economics, People, Process
III_4	What is the establishment's busiest day, in terms of number of meals served?		
III_5	Are any foods prepared or partially prepared at a commissary or other location?	Describe whether foods are prepared at commissaries.	Process
III_6	Other than daily specials, when was the last time food items were added to your menu(s)?	Describe whether food items have been added to the menu.	Food, People, Process
III_7	Where does the establishment purchase or acquire its food?	Describe establishment food sources.	Process
III_8	In total how long have you worked as a kitchen manager?	Describe manager experience.	People, Process
III_9	Approximately how long have you been employed as a kitchen manager in this establishment?		
III_10	How many kitchen managers, including you, are currently employed in this establishment?	Describe ratio of managers to workers (measure of worker supervision).	People
III_11	What language(s) do you and other managers in this establishment speak fluently? (Check all that apply)	Describe manager/worker communication/language barriers.	People
III_12	What languages do you and other managers speak at work? (Check all that apply		
III_13	In your opinion, how well do you communicate verbally with your food workers, very well, somewhat well or not well at all?		
III_14	Do any kitchen managers receive food safety training?	Describe manager food safety training.	People
III_14a	How many kitchen managers have had food safety training?		
III_14b	What type of food safety training do kitchen managers (you) receive?		
III_15	Does this establishment require that kitchen managers have a food safety certification?	Describe food safety certification.	People
III_16	Are any kitchen managers, including you, food safety certified?		
III_16a	How many kitchen managers in this establishment, including yourself, are food safety certified by an ANSI accredited program such as ServSafe National Registry of Food Safety Professionals/Environmental Health Testing or Thomson Prometric?		

III_17	How many food workers do you have?	Describe staff size.	People, Process
III_18	What language(s) do food workers in this	Describe manager/worker communication/language barriers.	People
	establishment speak fluently		
III_19	What languages do food workers speak at		
	work?		
III_20	Do any food workers receive food safety	Describe food worker food safety	People
	training?	training.	
III_20a	How many food workers have had food		
	safety training?	-	
III_20b	What type of food safety training do food		
TTT 01	workers receive?		
III_21	Does this establishment have a cleaning	Describe cleaning policies.	Process
III 04	policy or schedule for the <u>kitchen floor</u> ?	-	
III_21a	Is this policy written?	-	
III_22	Does this establishment have a cleaning		
	policy or schedule for the <u>refrigerator</u>		
III 22a	units, such as a walk-in or reach-in?	-	
III_22a	Is this policy written?	-	
III_23	Does this establishment have a cleaning		
III_24	policy or schedule for the <u>cutting boards</u> ?	-	
111_24	Does this establishment have a cleaning policy or schedule for the <u>food slicers</u> ?		
III_24a	Is this policy written?	-	
III_24a III_25	Does this establishment have a cleaning	-	
111_23	policy or schedule for the <u>food preparation</u>		
	tables?		
III_25a	Is this policy written?	-	
III_25a	Does this establishment have a policy	Describe glove use policies.	Process
111_20	concerning disposable glove use?	Describe giove use policies.	1100035
III_27	Does the glove policy require that food		
····_ - /	workers wear gloves:		
III_27a	at all times while working in the	1	
	kitchen?		
III_27b	when handling ready-to-eat foods?	1	
III_27c	when handling raw meat or poultry?	1	
III_27d	when they have cuts or other skin	1	
_	injuries?		
III_28	Does this establishment have a policy to	Describe temperature taking and	Process
	take the temperature of any incoming food	recording policies/practices.	
	products?		
III_28a	Are temperatures of incoming products		People
	recorded?		
III_29	Excluding incoming products, does this		Process
	establishment have a policy to take food		
	temperatures?	_	
III_29a	Are these food temperatures recorded?		People
III_30	Does this establishment have a policy or	Describe ill worker policies.	People
	procedure that requires food workers to		
	tell a manager when they are ill?	4	
III_30a	Is this policy in writing?	-	
III_30b	Does this policy require ill workers to tell		
	managers what their symptoms are?		

III_30c	Does this policy specify certain symptoms that ill workers are required to tell managers about?		
III_30c1	What are those symptoms? (Check all that apply)		
III_30d	Does this policy apply to kitchen managers as well as food workers?		
III_31	When food workers say they are ill, do you typically ask if they are experiencing certain symptoms?		
III_31a	What are those symptoms? (Check all that apply)		
III_32	Does this establishment have a policy or procedure to restrict or exclude ill workers from working?		
III_32a	Is this policy in writing?	-	
III_32b	Does this policy specify the specific symptoms that would prompt excluding or restricting ill workers from working?		
III_32b1	What are those symptoms? (Check all that apply)		
III_32c	Does this policy apply to kitchen managers as well as food workers?		
III_33	Do any kitchen managers (you) ever get paid when they miss work because they are ill?	Describe paid sick leave policies.	People
III_33a	How many kitchen managers get paid when they miss work because they are ill?		
III_34	Do any food workers ever get paid when work is missed because they are ill?		
III_34a	How many food workers get paid when they miss work because they are ill?		

Part IV: E	Part IV: Establishment Observation			
IV_2	Are hand sinks available in the employee	Describe availability of handwashing	Equipment	
	restroom(s)?	sinks, supplies and equipment.		
IV_2a	How many hand sinks are in the employee			
	restrooms?			
IV_2b	Is warm water (minimum 100°F) available			
	at all employee restroom hand sinks?			
IV_2c	Is soap available at (or near) all employee			
	restroom hand sinks?			
IV_2d	Are paper or cloth drying towels available			
	at (or near) all employee restroom hand			
	sinks?			
IV_3	Is a hand sink available in the work			
	area(s)?			
IV_3a	How many hand sinks are located in the			
	work area(s)?			
IV_3b	Is warm water (minimum 100°F) available			
	at all hand sinks in the work area?			

IV_3c	Is soap available at (or near) all hand sinks in the work area?		
IV_3d	Are paper or cloth drying towels available at (or near) all hand sinks in the work area?		
IV_4	Are there cold storage units in the establishment?	Describe cold storage units and their temperatures.	Equipment
IV_4a	How many cold storage units are in the establishment?		
IV_4b	Which types of units did you observe?		
IV_5	Are all cold storage areas maintained at a temperature of 41°F or below?		
IV_5a	How many cold storage units are above 41°F?		
IV_6	Are any food workers using gloves while handling food?	Describe glove practices.	Equipment
IV_7	Is there a supply of disposable gloves available in the establishment?	Describe glove availability.	Economics, Equipment
IV_8	Are any food workers handling RTE foods with bare hands?	Describe bare hand contact practices.	People
IV_9	Are there records to indicate that the temperatures of incoming ingredients are being taken and recorded?	Describe temperature taking and recording practices.	People
IV_10	Are there records to indicate that the temperatures of foods, excluding incoming ingredients, are being taken and recorded?		
IV_11	Is there any evidence of direct cross contamination of raw animal products with ready to eat foods?	Describe practices that could lead to cross contamination.	People, Process
IV_12	Is there cooling of hot foods in this establishment?	Describe food cooling practices.	Process
IV_12a	What cooling method(s) are used?	-	
IV_13	Were any foods observed in hot holding?	Describe food holding practices.	People, Process
IV_13a	Were the temperatures of any foods in hot holding measured?		
IV_13b	Were the temperatures of all foods measured in hot holding at 135°F or above?		
IV_14	Were any foods observed in cold holding?		
IV_14a	Were the temperatures of any foods in cold holding measured?		
IV_14b	Were the temperatures of all foods measured in cold holding at 41°F or below?		
IV_15	Were any foods observed during cooking?	Describe cooking practices.	People, Process
IV_15a	Were the temperatures of any foods being cooked measured?		
IV_15b	Were the temperatures of all foods measured during cooking at the recommended temperatures?		
IV_16	Are wiping cloths used in the	Describe wiping cloth practices.	Equipment,

IV_16a	Are all wiping cloths stored in a sanitizer		
1v_10d	solution between uses?		
IV 17	Are there mechanical washing machines	Describe dishwashing practices.	Equipment,
IV_17	for dishes, utensils, or other equipment?		Process
	Does the wash cycle reach the	-	
IV_17a	temperatures recommended for that		
	washing machine?		
	Does the sanitizing cycle reach the		
IV_17b	temperatures recommended for		
	sanitization?		
IV_17c	Is chemical sanitizing used?		
	Did the chemical sanitizing cycle have the		
IV_17d	required levels of chemical sanitizer		
	recommended for the machine?		
IV 10	Are there any hand washed dishes, utensils		
IV_18	or other equipment?		
	Are hand washed dishes, utensils or other		
IV_18a	equipment washed and sanitized (either		
	with heat or chemical)?		
IV_18b	Is the sanitizing method (heat or chemical)	-	
11,100	properly implemented?		
IV_19	Did you observe signs and instructions	Describe signs.	People, Process
11,13	posted in the establishment?		
	Did any signs or posted instructions use		
IV_19a	pictures or symbols to communicate a		
	message?		
IV_19b	What languages did you observe on signs		
14-130	or instructions posted for food workers?		

Part V:	Suspected/Confirmed Food		
V_5	Which of the following best describes the	Describe and classify the food prep	Process
_	food preparation process used for this	processes that the establishment used to	
	specific ingredient or multi-ingredient	prepare the suspected/confirmed	
	food before consumption?	vehicle.	
V_6	During the likely time the ingredient / food	Out-of-the ordinary events can lead to	Process
	was prepared, were any events noted that	potential food safety risks. These data	
	appeared to be different from the ordinary	will identify and describe these events.	
	operating circumstances or procedures as		
	described by managers and / or workers?		
V_6a	If yes, how would they be best		
	characterized		
V_7	Name of the single specific ingredient	Describe and classify food ingredients	Food
V_8	Is the ingredient an animal product?	linked with the outbreak.	
V_8a	Select the type of animal product		
V_8b	If Poultry, select the type		
V_8c	If Seafood, select the type		
V_8d	For beef, poultry, pork, lamb, and seafood		
	products select the best description of the		
	product upon arrival at the foodservice		
	establishment		
V_8e	For dairy, select the best description of the		
	product upon arrival at the foodservice		
	establishment		
V_8f	For eggs, select the best description of the		
	product upon arrival at the foodservice		
	establishment		
V_9	Is this ingredient a plant or plant product?		
V_9a	Select the type of plant product		
V_9b	If Produce, select type (Select only one		
V_9c	Provide the best description of the plant		
	product upon arrival of the product to the		
	foodservice establishment		
V_10	Was the ingredient described in question 8		
	or 9?		
V_10a	Please describe the ingredient		
	class/category?		
V_11	Is any information present (product	Describe the origin of the food.	Food
	manifests, records, tags, etc.) that shows		
	ingredient is an imported food item?		

Number	Question	Justification
VII_1	Were any contributing factors	Describe whether contributing factors where
	identified in this outbreak?	identified.
VII_4	Were any Contamination Factors	Describe whether contamination factors were
	identified in this foodborne illness	identified.
	outbreak?	
VII_4a	How many Contamination Factors	Describe how many contamination factors were
	were identified in this outbreak?	identified.
VII_5	Were any Proliferation/Amplification	Describe whether proliferation factors were
	Factors identified in this foodborne	identified.
	illness outbreak?	
VII_5a		Describe how many proliferation factors were
	Factors were identified in this	identified.
	outbreak?	
VII_6	Were any Survival Factors identified	Describe whether survival factors were identified.
	in this foodborne illness outbreak?	
VII_6a	How many Survival Factors were	Describe how many survival factors were identified.
	identified in this outbreak?	
VII_7	Which Contributing Factor was	Describe the specific contributing factors identified
	identified?	in the outbreak.
VII_8	In your judgment, was this the	Describe whether the contributing factors were
	primary contributing factor for this	primary contributing factors.
	outbreak?	
VII_8a	Briefly explain why this is a	Describe how contributing factors are identified.
	contributing factor in this outbreak.	
VII_10	When did this factor most likely	Describe when the contributing factors occurred.
	occur?	

Table B.4.4. Variables included in descriptive analyses of contributing factors

To address the third goal of this data collection, *describe the associations between environmental antecedents and contributing factors*, we will conduct tests for association and logistic regression models.

Analysis will involve bivariate tests for association between individual environmental antecedent (explanatory) variables and the contributing factor (outcome) variables. 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 environmental antecedent variables will be used as candidate "predictors" to examine their multivariate relationships with the contributing factor variables. Multivariable logistic regression will be used to model for the effects that these environmental antecedent variables have in explaining the variations observed in the contributing factor variables. This type of analysis allows us to determine which

environmental antecedents contribute to the presence of the contributing factor, and the relative degree of impact that each environmental antecedent has in the presence of that contributing factor. A separate model will be developed for each contributing factor analyzed.

Table B.4.5 describes the study questions designed to address this third goal of this data collection and the data collection variables designed to answer those questions. Note that we will likely create composite environmental antecedent variables based on the individual variables listed in the table.

	5	Contributing
Study Question	Environmental Antecedent Variables	Factors
How are specific environmental antecedents related to contamination contributing factors?	II_5, II_6, II_7, II_8, II_11, II_12, II_13, II_14, III_2, III_3, III_4, III_5, III_7, III_8, III_9, III_10, III_11, III_12, III_13, III_14 (a, b), III_15, III_16 (a), III_17, III_18, III_19, III_20 (a, b), III_21 (a), III_22 (a), III_23 (a), III_24 (a), III_25 (a), III_26 (a), III_27 (a,b,c,d), III_30 (a,b,c,d), III_31 (a), III_32 (a, b, c), III_33 (a), III_34 (a), IV_2 (a, b, c, d), IV_3 (a, b, c, d), IV_6, IV_7, IV_8, IV_11, IV_16 (a), IV_17 (a, b, c, d), IV_18 (a, b), IV_19 (a,b), IV_20, V_1 (a), V_2, V_3, V_4, V_5, V_6 (a), V_7, V_8 (a,b,c,d,e,f), V_9 (a,b,c), V_10 (a), V_11	C1-C15
How are specific environmental antecedents related to proliferation contributing factors?	II_5, II_6, II_11, II_13, II_14, III_2, III_3, III_4, III_5, III_6, III_8, III_9, III_10, III_11, III_12, III_13, III_14 (a, b), III_15, III_16 (a), III_17, III_18, III_19, III_20 (a, b), III_28 (a), III_29 (a), IV_4 (a, b), IV_5 (a, b), IV_12 (a), IV_13 (a), IV_14 (a)	P1-P12
How are specific environmental antecedents related to survival contributing factors?	II_5, II_6, II_13, II_14, III_2, III_3, III_4, III_5, III_6, III_8, III_9, III_10, III_11, III_12, III_13, III_14 (a, b), III_15, III_16 (a), III_17, III_18, III_19, III_20 (a, b), III_29 (a), IV_15 (a)	S1-S5

Table B.4.5. Study	questions and the data collection variables designed to answer those q	uestions
Tuble Diffiol Oldu	questions and the data concerton variables designed to answer those q	aconono

Table B.4.6 is a table shell that illustrates how we might analyze and present the data examining the bivariate relationships between specific environmental antecedents and the contributing factor of bare-hand contact with ready-to-eat food by a food worker who is suspected to be infectious (contributing factor C10).

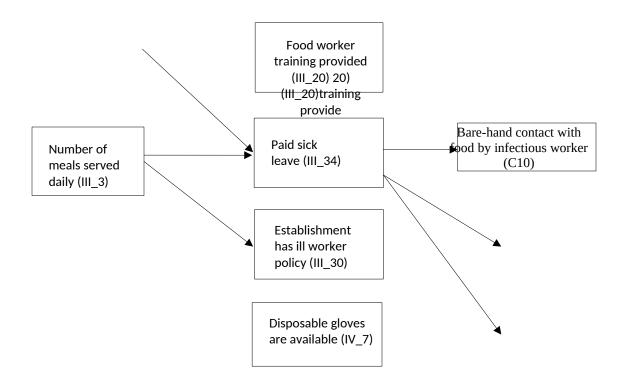
	Bare hand contact with food by infectious food worker (C10) identified as a contributing factor	
Environmental antecedent variables		
	OR (95% CI)	Р
Number of meals served daily (III_3)	· ·	
<300	x.xx (ref)	.XXX
<u>≥</u> 300	X.XX	
Food worker training provided (III_20)		
No	x.xx (ref)	.XXX
Yes	X.XX	
Paid sick leave provided (III_34)		
No	x.xx (ref)	.XXX
Yes	X.XX	
Establishment has ill worker policy (III_30)		
No	x.xx (ref)	.XXX
Yes	X.XX	
Disposable gloves are available in establishment		
(IV_7)		
No	x.xx (ref)	.XXX
Yes	X.XX	
Hand sink is available in work area (IV_3)		
No	x.xx (ref)	.XXX
Yes	X.XX	

Table B.4.6. Example Table Shell: Environmental antecedent variables associated with the outcome variable of whether the contributing factor of bare-hand contact with ready-to-eat food by an infectious food worker was identified, bivariate analyses

OR=Odds Ratio, P=probability level

Below is an example figure demonstrating results from a multivariate analysis of the associations between environmental antecedents and the contributing factor of bare-hand contact with ready-to-eat food by an infectious food worker. This type of analysis allows us to determine the relationships among environmental antecedents and between environmental antecedents and contributing factors. It allows us to determine the direct and indirect effects of each environmental antecedent on the contributing factor. A separate model would be developed for each contributing factor analyzed.

Table B.4.7. Example Table Shell- Environmental antecedent variables associated with the outcome variable of whether the contributing factor of bare-hand contact with ready-to-eat food by an infectious worker was identified, multivariate analyses



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

The following persons were primarily responsible for designing the instrument however, Laura Brown, Erik Coleman, and Vince Radke will be primarily responsible for analyzing data.

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