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).

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

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| **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 laboratory data reported to the state. |
| I\_8a | Select the state or local surveillance system(s) where this outbreak was reported. |
| I\_9 | Was this outbreak reported to a national surveillance system? | This information will be used to help connect the NEARS data to existing epidemiological and laboratory data reported to other national surveillance systems. |
| I\_9a | Select the national surveillance system(s) where this outbreak was reported and record the corresponding reporting number. |
| V\_1 | Was a specific ingredient or multi-ingredient food suspected or confirmed in this outbreak? | Describe ingredients and foods associated with the 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 single specific ingredient or multi ingredient food was implicated in the outbreak. | Describes the type of information used to determine the food associated with 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 outbreak? | Describe if contributing factors where identified in an outbreak investigation. |

**Table B.4.2. Variables included in descriptive analyses of outbreak responses**

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| **Question Number** | **Question** | **Justification** |
| 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 specific environmental assessment activities are conducted. |
| IV\_1 | Date observations were made |
| VI\_1 | Were any samples taken? | Describe how many samples and what type are taken during environmental assessments. |
| VI\_2 | How many samples were taken? |
| 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.4.3for 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.4.4for 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.

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

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| **Question Number** | **Question** | **Justification** | **Classification** |
| **Part II: Establishment description, categorization 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? *(Check all that apply)* |  | People |
| 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 establishment speak fluently | Describe manager/worker communication/language barriers. | People |
| III\_19 | What languages do food workers speak at work? |  |
| III\_20 | Do any food workers receive food safety training? | Describe food worker food safety training. | People |
| III\_20a | How many food workers have had food safety training? |
| III\_20b | What type of food safety training do food workers receive? |
| III\_21 | Does this establishment have a cleaning policy or schedule for the kitchen floor? | Describe cleaning policies. | Process |
| III\_21a | Is this policy written? |
| III\_22 | Does this establishment have a cleaning policy or schedule for the refrigerator units, such as a walk-in or reach-in? |
| III\_22a | Is this policy written? |
| III\_23 | Does this establishment have a cleaning policy or schedule for the cutting boards? |
| III\_24 | Does this establishment have a cleaning policy or schedule for the food slicers? |
| III\_24a | Is this policy written? |
| III\_25 | Does this establishment have a cleaning policy or schedule for the food preparation tables? |
| III\_25a | Is this policy written? |
| III\_26 | Does this establishment have a policy concerning disposable glove use? | Describe glove use policies. | Process |
| III\_27 | Does the glove policy require that food workers wear gloves: |
| III\_27a | …at all times while working in the kitchen? |
| III\_27b | …when handling ready-to-eat foods? |
| III\_27c | …when handling raw meat or poultry? |
| III\_27d | …when they have cuts or other skin injuries? |
| III\_28 | Does this establishment have a policy to take the temperature of any incoming food products? | Describe temperature taking and recording policies/practices. | Process |
| III\_28a | Are temperatures of incoming products recorded? | People |
| III\_29 | Excluding incoming products, does this establishment have a policy to take food temperatures? | Process |
| III\_29a | Are these food temperatures recorded? | People |
| III\_30 | Does this establishment have a policy or procedure that requires food workers to tell a manager when they are ill? | Describe ill worker policies. | People |
| 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? |

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| **Part IV: Establishment Observation** | | | |
| IV\_2 | Are hand sinks available in the employee restroom(s)? | Describe availability of handwashing sinks, supplies and equipment. | 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 establishment? | Describe wiping cloth practices. | Equipment, Process | |
| IV\_16a | Are all wiping cloths stored in a sanitizer solution between uses? |
| IV\_17 | Are there mechanical washing machines for dishes, utensils, or other equipment? | Describe dishwashing practices. | Equipment, Process | |
| IV\_17a | Does the wash cycle reach the temperatures recommended for that washing machine? |
| IV\_17b | Does the sanitizing cycle reach the temperatures recommended for sanitization? |
| IV\_17c | Is chemical sanitizing used? |
| IV\_17d | Did the chemical sanitizing cycle have the required levels of chemical sanitizer recommended for the machine? |
| IV\_18 | Are there any hand washed dishes, utensils or other equipment? |
| IV\_18a | Are hand washed dishes, utensils or other equipment washed and sanitized (either with heat or chemical)? |
| IV\_18b | Is the sanitizing method (heat or chemical) properly implemented? |
| IV\_19 | Did you observe signs and instructions posted in the establishment? | Describe signs. | People, Process | |
| IV\_19a | Did any signs or posted instructions use pictures or symbols to communicate a message? |
| IV\_19b | What languages did you observe on signs or instructions posted for food workers? |

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| **Part V: Suspected/Confirmed Food** | | |  |
| V\_5 | Which of the following best describes the food preparation process used for this specific ingredient or multi-ingredient food before consumption? | Describe and classify the food prep processes that the establishment used to prepare the suspected/confirmed vehicle. | Process |
| V\_6 | During the likely time the ingredient / food was prepared, were any events noted that appeared to be different from the ordinary operating circumstances or procedures as described by managers and / or workers? | Out-of-the ordinary events can lead to potential food safety risks. These data will identify and describe these events. | Process |
| V\_6a | If yes, how would they be best characterized |
| V\_7 | Name of the single specific ingredient | Describe and classify food ingredients linked with the outbreak. | Food |
| V\_8 | Is the ingredient an animal product? |
| 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 manifests, records, tags, etc.) that shows ingredient is an imported food item? | Describe the origin of the food. | Food |

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

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| **Number** | **Question** | **Justification** |
| VII\_1 | Were any contributing factors identified in this outbreak? | Describe whether contributing factors where identified. |
| VII\_4 | Were any Contamination Factors identified in this foodborne illness outbreak? | Describe whether contamination factors were identified. |
| VII\_4a | How many Contamination Factors were identified in this outbreak? | Describe how many contamination factors were identified. |
| VII\_5 | Were any Proliferation/Amplification Factors identified in this foodborne illness outbreak? | Describe whether proliferation factors were identified. |
| VII\_5a | How many Proliferation/Amplification Factors were identified in this outbreak? | Describe how many proliferation factors were identified. |
| VII\_6 | Were any Survival Factors identified in this foodborne illness outbreak? | Describe whether survival factors were identified. |
| VII\_6a | How many Survival Factors were identified in this outbreak? | Describe how many survival factors were identified. |
| VII\_7 | Which Contributing Factor was identified? | Describe the specific contributing factors identified in the outbreak. |
| VII\_8 | In your judgment, was this the primary contributing factor for this outbreak? | Describe whether the contributing factors were primary contributing factors. |
| VII\_8a | Briefly explain why this is a contributing factor in this outbreak. | Describe how contributing factors are identified. |
| VII\_10 | When did this factor most likely occur? | Describe when the contributing factors occurred. |

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.

**Table B.4.5. Study questions and the data collection variables designed to answer those questions**

|  |  |  |
| --- | --- | --- |
| **Study Question** | **Environmental Antecedent Variables** | **Contributing 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.4.6 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).

**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**

|  |  |  |
| --- | --- | --- |
| **Environmental antecedent variables** | **Bare hand contact with food by infectious food worker (C10) identified as a contributing factor** | |
|  | OR (95% CI) | P |
| Number of meals served daily (III\_3) |  |  |
| <300 | x.xx (ref) | .xxx |
| >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 |  |

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**

Bare-hand contact with food by infectious worker (C10)

Food worker training provided (III\_20) 20)(III\_20)training provide

Disposable gloves are available (IV\_7)

Number of meals served daily (III\_3)

Paid sick leave (III\_34)

Establishment has ill worker policy (III\_30)

**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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