

NEARS

National Environmental Assessment Reporting System

Instruction Manual

National Center for Environmental Health
Division of Emergency and Environmental Health Services



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The National Environmental Assessment Reporting System (NEARS), formerly known as the National Voluntary Environmental Assessment Information System (NVEAIS), began data collection in April 2014.

Use of trade names is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service, or the U.S. Department of Health and Human Services.

List of Acronyms

ANSI	American National Standards Institute
CDC	Centers for Disease Control and Prevention
CIFOR	Council to Improve Foodborne Outbreak Response
EA	environmental assessment
FDA	U.S. Food and Drug Administration
IAFP	International Association for Food Protection
NEARS	National Environmental Assessment Reporting System
NORS	National Outbreak Reporting System
PHF	potentially hazardous food
TCS	time/temperature control for safety
WGS	whole genome sequencing

Background/General Notes

The National Environmental Assessment Reporting System (NEARS) is a surveillance system—an organized infrastructure that enables ongoing, systematic collection, management, analysis, interpretation, and dissemination of foodborne illness outbreak EA (environmental assessment) data. The system, formerly known as the National Voluntary Environmental Assessment Information System (NVEAIS), began data collection in April 2014.

NEARS users include local, state, tribal, territorial, and federal food regulatory agencies throughout the United States. Data reported to NEARS will be used to

- Characterize food vehicles and monitor trends.
- Identify and monitor contributing factors and environmental antecedents.
- Generate hypotheses.
- Guide planning, implementation, and evaluation of food safety programs.
- Prevent future outbreaks.

NEARS uses the 2017 U.S Food and Drug Administration (FDA) Model Food Code (FDA 2017) as the food safety standard for conducting EAs. Different programs may use their respective state or county code while performing a foodborne illness investigation. However, the FDA code provides a national food safety standard that allows for uniform data collection, management, analysis, and interpretation of the data provided.

This means data reported to NEARS may not be a violation of local code, but would be a violation in NEARS. For example,

- A cold holding unit is holding time/temperature control for safety (TCS) foods at 44°F.
- The local/state ordinance allows a maximum cold holding temperature of 45°F.
- The person conducting the EA would cite it as out of temperature in NEARS, but would not mark it as a violation of the local code as a part of the investigation report.

Also, it is important to note that improper food-handling practices may be seen in a facility, but have nothing to do with the etiologic agent nor do they contribute to the source of the outbreak. Information about these kinds of improper food-handling practices will allow a comparison of practices between facilities. For example,

- A cold holding issue may be identified during the investigation of a norovirus outbreak.
- Cold holding would have no effect on the amplification or survival of norovirus.
- Cold holding should not be considered a contributing factor to the outbreak, but the improper cold holding information should still be recorded on the appropriate NEARS form.

Additionally, data reported to NEARS should be based on a foodborne illness outbreak EA, not on an inspection. Individuals collecting or reporting data to NEARS are strongly encouraged to first take CDC's free e-learning course on conducting environmental assessments as a part of conducting foodborne illness outbreak investigations (<https://www.cdc.gov/nceh/ehs/elearn/eats/index.html>).

Data collected by NEARS may be modified in the future per user recommendations. The most recent revision of the data collection instrument was for the 2020 NEARS version.

Terms and Methods

The following terms are introduced to aid in the use of this manual. A complete list of terms and their intended meanings in this manual is provided in the Definitions section.

Foodborne Illness Outbreak

A foodborne illness outbreak is defined as two or more cases of a similar illness resulting from ingestion of a common food in the United States (*Reference: CDC National Outbreak Reporting System*). All outbreaks associated with a retail food establishment should be reported to NEARS. It is often difficult at the outset of an outbreak investigation to know if transmission is due to food only or if it is due to person-to-person contact or a combination of food and person-to-person contact. Unless data are available to support the outbreak mode of transmission as exclusively person-to-person contact, please report all retail food establishment linked outbreaks to NEARS.

Environmental Assessment (EA)

An EA is the systems-based component of an outbreak investigation that fully describes how the environment contributed to the introduction and/or transmission of agents that cause or could cause illness. Environment is everything external to the host, including air, food, water, animals, plants, climate, etc. as well as people, social, and built environments. All aspects of the external environment can be listed as variables that, in relation to transmission, are neutral, conducive, or protective. Contributing factors and environmental antecedents to an outbreak can be determined from this description.

An EA may encompass a range of activities based on the type of outbreak under investigation, how the outbreak was identified, and the suspected route of transmission involved. In foodborne illness outbreaks, EAs are conducted at every point along the farm-to-fork food continuum that is suspected of contributing to the outbreak. Assessment activities include, but are not limited to:

- Reviewing and/or collecting records related to the growth, harvest, processing, distribution, and/or handling of foods at the point of final service.
- Interviewing people who have direct knowledge of how food was grown, harvested, processed, distributed, and/or handled at point of final service.
- Developing food flows to determine points of contamination; proliferation and/or amplification; and survival of pathogens, toxins, or other agents involved in the outbreak.

Environmental Antecedents

Environmental antecedents are the conditions leading to the contamination, survival, or increase of biological or chemical agents in food. They may be related to people, equipment, food process, food type, economics, or other circumstances. In other words, environmental antecedents are the reason why contributing factors occur. Environmental antecedents are sometimes referred to as root causes of outbreaks.

Technical Assistance

CDC staff will provide technical assistance to NEARS participants by phone, email, and quarterly conference calls for all participants. Participants can send any NEARS-related questions to NEARS@cdc.gov. Phone contact information will be provided to participants during NEARS registration.

Good Practices

Based on feedback from our partners and the types of questions that have been fielded by NEARS staff, we offer these general practices to be considered by programs participating in NEARS.

- The EA and data collected for NEARS are intended to supplement the foodborne illness investigation, not replace it. There is still a need to evaluate practices and conditions in the suspected food facility that are not captured in the EA. This information should be combined with epidemiological and laboratory support.
- If the evidence supporting a suspected foodborne illness outbreak is strong enough to warrant an investigation, we recommend completing an EA even if the outbreak is not laboratory confirmed.
- The earlier an EA is conducted in an investigation, the more likely a contributing factor to the outbreak will be identified. Initial analyses of NEARS data indicated that the earlier an EA was performed the more likely a contributing factor would be identified. We recommend conducting an EA as early in the investigation as possible.
- While a positive sample is extremely important, understanding the entirety of the samples that were taken and their results provides additional valuable information. We recommend recording and submitting data on all environmental samples taken—even the negative ones.
- Many of the NEARS manager interview questions simply ask whether the policies exist. This is not meant to keep a program from looking at the policies or asking other questions about the policies and their content.
- Some information, such as the questions in Part I (General Characteristics), may not be known at the time the EA is conducted. This information is meant to be completed at the end of the outbreak investigation.
- Many of the questions in this manual are clear cut, but we recommend you review the marking instructions in this manual before going to the field. The marking instructions have been modified based on feedback from participating programs to clarify the intent of the question and how an item should be marked.
- The intent of NEARS is to systematically gather information on the practices occurring in outbreak-associated food establishments, and then assess the underlying contributing factors and environmental antecedents. With this in mind, it is important to gather as complete information as possible, even if it may not be relevant to the investigation at hand.
- Data reported to NEARS should include information gathered from all visits related to the EA. These visits may range from an initial site visit in response to an illness complaint to all subsequent visits necessary to complete the EA. The cumulative data collected during the entirety of the EA may include essential information to report in the Manager Interview (Part III) and Observation (Part IV). This information is also important to review after the EA in order to select and identify contributing factors and environmental antecedents.

MOST IMPORTANTLY—if you need assistance, please contact NEARS@cdc.gov.

NEARS Reporting and Reporting Forms

NEARS is *not* designed to be a comprehensive environmental assessment tool: NEARS is a repository where federal, state, local, or tribal programs report some of their EA data.

We expect programs will conduct their EAs and then report some of the data to NEARS. Thus, most of the NEARS reporting forms do not need to be taken into the field while conducting an EA. For example,

- Part I asks for descriptive information about the outbreak (e.g., the etiologic agent) and would be completed at the end of the investigation.
- Parts III-IV (Manager Interview and Establishment Observation, respectively) ask for specific data that may or may not be collected during an EA. We recommend using those forms in the field to ensure collection of all NEARS information.

The NEARS reporting form is divided into seven parts. This manual addresses each part of the reporting form, including the purpose of each part, an explanation for each question, and the type of response expected.

The seven parts of the NEARS report forms are as follows:

- Part I (General Characterization of the Outbreak Response) provides the epidemiological context for the outbreak and basic information regarding the response required. This section links all EAs conducted with a single outbreak event. **Part I is filled out for each outbreak event.** This information is based on the completed outbreak investigation.
- Part II (Establishment Description, Categorization, and Menu Review) gathers basic information about the response including the need for a translator, type of establishment, and menu. **Part II is filled out one time for each establishment involved in an outbreak event. Field staff may use this form in the field as part of the initial visit.** This information is based on the completed outbreak investigation.
- Part III (Manager Interview) characterizes the policies and practices in the establishment based on a manager interview conducted during the foodborne illness outbreak EA. This section includes general interview questions related to the establishment as well as questions about kitchen managers, food workers, and establishment policies. The Manager Interview provides a semi-structured interview to ensure accurate, consistently reported information. **Part III is filled out one time for each establishment involved in an outbreak. Field staff may use this form in the field as part of the initial visit.** This information is intended to be gathered during the initial establishment visit of the outbreak investigation—**preferably within 24-48 hours of the establishment being identified for an EA.**
- Part IV (Establishment Observation) collects information concerning the establishment based on observations of conditions and practices during the initial EA visit. These observations should describe existing circumstances and practices before employees become influenced by the fact that an outbreak investigation is under way. **Part IV is filled out one time for each establishment involved in an outbreak. Field staff may use this form in the field as part of the initial visit.** This information is based on the initial establishment visit of the outbreak investigation—**preferably within 24-48 hours of the establishment being identified for an**

EA. Observational data collected during a foodborne illness complaint that leads to an EA or observational data collected by rapid responders may be used to complete this section.

- Part V (Suspected/Confirmed Food) collects information on the suspected or confirmed food vehicle. This information is based on the completed outbreak investigation. **Part V is filled out one time for every suspected/confirmed food item associated with the outbreak.**
- Part VI (Positive Samples) provides information on environmental or food sampling. Information collected in Part VI does not include human clinical samples. This information is based on the completed outbreak investigation. **Part VI is filled out one time for every positive sample associated with the outbreak.**
- Part VII (Contributing Factors) describes factors that introduce or otherwise permit contamination, proliferation/amplification, and survival of pathogens. Part VII is filled out for each outbreak event. This information is based on the completed outbreak investigation. **Part VII is filled out once for each outbreak.**

Many foodborne illness outbreak investigations occur locally and involve only one—or possibly two—retail food service establishments. Other foodborne illness outbreak investigations may involve multiple retail food service establishments, especially if a food was contaminated before receipt by the food establishments. Information on both types of outbreak situations should be reported to NEARS. For locally occurring outbreak investigations, all sections of the reporting form should be submitted. If more than one establishment is involved, all sections of the reporting form should be provided for each establishment involved and for each establishment where an EA was conducted.

In situations where an outbreak is the result of a food contaminated before receipt by the food establishment, contact CDC at NEARS@cdc.gov for guidance. Generally, at a minimum, the following reporting form parts should be completed for this scenario:

- Part I: General Characterization of the Outbreak Response,
- Part V: Suspected/Confirmed Food,
- Part VI: Positive Samples, and
- Part VII: Contributing Factors (citing C7).

Summary of Anticipated Forms

Form	Local Outbreak	Supplier-Based Outbreak
Part I: General Characterization of Outbreak	X	X
Part II: Establishment Description, Categorization, Menu Review	X	
Part III: Manager Interview	X	
Part IV: Establishment Observation	X	
Part V: Suspected/Confirmed Foods	X	X
Part VI: Positive Samples	X	X
Part VII: Contributing Factors	X	X (C7)

Part I: General Characterization of the Outbreak Response

Purpose of Part I: Part I characterizes the outbreak associated with the reported environmental assessments (EAs). It also facilitates linking the data in NEARS to epidemiological and laboratory data that is reported to CDC's National Outbreak Reporting System (NORS). Questions in this section are based on the following assumptions:

- Some form of collaboration routinely occurs between the food regulatory program reporting EA data into NEARS and the appropriate communicable disease control program during all foodborne illness outbreak investigations.
- Foodborne illness outbreaks are reported to NORS as appropriate.

If outbreak data are reported to both NORS and NEARS, the data can be linked. For this to be possible, reported outbreaks must include the NORS and NEARS reporting numbers and the state ID number. Complementary data in both systems can provide a more comprehensive picture of the outbreak. The new data entry dashboard combines NEARS and NORS data entry platforms, and users will be able to link NEARS and NORS data. Users will be able to generate reports, create data visualizations, and import and export their data.

Outbreak data do not have to be reported to NORS to be entered into NEARS. There may be occurrences when outbreak data may not be reported to NORS; however, any EA data that are collected as a part of an outbreak investigation should be reported to NEARS. This reporting would include submitting data for outbreaks with both confirmed and suspected etiologies.

Purpose of Questions 1-7: These questions characterize the:

- scope of the outbreak,
- the number of EAs conducted in response to a specific outbreak and
- the suspected or confirmed primary agent in the outbreak (if known).

This information classifies outbreaks as single event outbreaks or larger multistate or national outbreaks and helps to quantify the response to this outbreak event(s).

1. Did the exposure(s) take place in single or multiple locations (ex: one restaurant or two or more restaurants, one restaurant or a restaurant, and a school)?

- Select *Single Location* if the exposure(s) took place in one physical location—for example, one restaurant, cafeteria, or school. If *Single Location*, → (skip to question 3)
- Select *Multiple Locations* if more than one restaurant, cafeteria, or school or a combination of establishments was involved.

2. Did the exposure(s) occur in a single state or multiple states?

- Select *Single State* if only one state were involved in the outbreak or if you are unaware that any other states were involved or implicated in this outbreak.
- Select *Multiple States* if you know more than one state was involved.

Base your response on the epidemiological information available after the outbreak investigation.

3. Did the exposure(s) happen in a single county/township/parish or multiple counties/townships/parishes?

- Select *Single* if only one county, township, or parish was involved.
- Select *Multiple* if more than one county, township or parish was involved.

4. How many food service establishment locations within your jurisdiction were associated with this outbreak?

Report the number of establishments in your jurisdiction that were reported to be associated with this outbreak. The number reported may be 1 or more. The answer to this question may be based on epidemiological or EA information. The question is intended to be as specific as possible about locations involved in this outbreak.

Example: The response to question 4 would be 1 if only 1 food service location were involved in the outbreak. However, the outbreak might be associated with chain X. Ten establishments of chain X are in the jurisdiction, and all 10 establishments were implicated due to a common contaminated food item. The response would be 10.

A food service establishment [subsequently referred to as an establishment] is defined as an operation that stores, prepares, packages, serves or vends food directly to the consumer or otherwise provides food for human consumption, such as a restaurant, school, catering business, or prison. Each establishment will have its own address, so if the business at the address changes, it becomes a different establishment. For this data collection, food service establishments do not include processing plants or establishments offering prepackaged foods that are NOT potentially hazardous.

5. How many environmental assessments were conducted at food service establishments in your jurisdiction as part of this outbreak?

Please record the number of EAs conducted in different establishments in your jurisdiction as part of this outbreak investigation. EAs are location specific. Multiple visits to a single establishment may occur while conducting an EA, but they are part of one EA. This number may be 1 or more. This number may or may not match the number reported in question 4. If ≥ 1 , \rightarrow (skip to question 6)

Example: Multiple establishments in a chain might be associated with a single outbreak event, but EAs were conducted in only a few. This might be due to limited program resources. It could be a situation where a contaminated product from a common source was involved in the outbreak, and the food handling practices at this chain are so consistent from establishment to establishment that a decision was made not to conduct EAs at all establishments.

In general, an EA at the retail food service level includes:

- a record review of the establishment,
- interviews with the manager and food workers,
- observation of food preparation and food preparation and storage areas,
- food flows for implicated foods/ingredients,
- environmental and food sampling, and
- any other reviews as needed to understand how and why food became contaminated.

However, depending on the type of outbreak and how the outbreak was identified, different components of the EA might not be conducted. For example, interviews or observations might not be conducted because a local program received information about an outbreak that was linked to a broader outbreak where the cause had already been determined and the issue was not at the retail level (e.g., the food item was determined to be a nut butter processed at one processing plant and distributed to multiple establishments).

In the above example, the local program might just conduct a records review and contact all implicated establishments to verify if they used the nut butter and had any purchasing records to confirm the purchase of implicated products. An EA in this example might only include a records review and maybe sampling if any nut butter products remained in the establishment at the time of the EA. Therefore, no information would be recorded for Part III (Manager Interview) or Part IV (Establishment Observation). In this scenario, record how many EAs were conducted.

Example: Spinach has been implicated in an *E. coli* outbreak. Serotypes or whole genome sequencing (WGS) allele codes have linked the cases, and the spinach has been linked back to a specific farm and specific lot numbers. A state/local outbreak investigation team might have local cases linked to this outbreak but might never conduct a manager interview, observations, or sampling in an establishment because they have records showing that the establishment used spinach that was part of the contaminated/suspected lot numbers, and all the spinach is gone. The investigation team would then have information to complete Part 1 (General Characterization of the Outbreak Response). Additionally, participation on a more prominent national team working on this outbreak and awareness of paperwork verifying the spinach was part of the recalled lots could mean that the state/local outbreak team has information to select the contributing factors for this outbreak in their jurisdiction.

5a. If no environmental assessments were conducted: Why were no environmental assessments conducted at food service establishments in your jurisdiction as a part of this outbreak?

Please provide a brief description of the reasons your jurisdiction did **NOT** conduct EAs at establishments. This question characterizes why EAs are not conducted. A program might not conduct any type of EA during an outbreak. For example:

- the jurisdiction might not have resources at the time of the outbreak and it might be decided that the outbreak is not enough of a public health threat to divert resources to conduct EAs,
- the jurisdiction could believe that the outbreak has been resolved and performing more EAs would not improve the understanding of what happened or change the outcome for the public, or
- the environmental and food safety officers might not have been engaged in the outbreak response.

6. How many non-food service establishments in your jurisdiction were associated with this outbreak?

Non-food service establishments include food distribution centers, warehouses, processing plants, manufacturers, or farms. If 0, → (skip to question 7)

Report the number of non-food service establishment locations associated with this outbreak. These non-food service establishment locations could be identified through traceback or other information collected or received from another agency by your jurisdiction during an outbreak investigation.

6a. *If non-food service establishments in your jurisdiction were associated with the outbreak: How many environmental assessments were conducted at non-food service establishments in your jurisdiction as part of this outbreak?*

Report if any EAs were conducted at non-food service establishments. EAs are location specific. Multiple visits to a single establishment may occur while conducting an EA, but they are part of one EA. Report the actual number of EAs conducted at non-food service establishments. If none were conducted, report 0 for this question. This number may or may not be the same as reported in question 6.

7. Was a primary agent identified (suspected or confirmed) in this outbreak?

- Select *Yes* if a primary or single-agent was identified (either confirmed or suspected) and characterize the agent in questions 7a.
- Select *No* if no one single or primary agent was identified. → (skip to question 8)

Agents are considered confirmed if they are confirmed, as determined by CDC guidelines:

https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/confirming_diagnosis.html

A single agent generally causes outbreaks, but sometimes more than one agent is involved in an outbreak.

7a. *If a primary agent was identified: What was the identified agent?*

Select the agent from the list provided. If the agent is not in the list provided, select *Toxic Agent, Other Agent, Chemical Agent, or Physical Hazard* as appropriate for the outbreak and describe the agent in the blank provided.

Purpose of Questions 8-9: These questions were added to the data reporting to help ensure that EA data can be linked to the correct epidemiological and laboratory outbreak data, so there is a complete picture of the outbreaks once all of the information has been reported.

8. Was this outbreak reported to a state or local Communicable Disease Surveillance Program?

- Select *Yes* if the outbreak was reported to your state or a local communicable disease control or epidemiology program.
- Select *No* if the outbreak was NOT reported to the state. → (skip to question 9)

8a. *If the outbreak was reported to a state or local program: Select the state or local surveillance system(s) where this outbreak was reported. (Check all that apply)*

Select the appropriate response to describe the surveillance systems where information from this outbreak was recorded. Provide the unique number used to identify and report this outbreak to the state and local surveillance system.

If no reporting number is used to report outbreaks to the state or locality, type N/A in the blank for the number.

9. Was this outbreak reported to a national surveillance system?

Tell us if data from this outbreak were reported to a national surveillance system. National surveillance systems include systems such as NORS, PulseNet, and CaliciNet.

Select *No* if the outbreak was NOT reported to the state. → (skip to question 10)

9a. If the outbreak was reported to a national program: Select the national surveillance system(s) where this outbreak was reported and record the corresponding reporting number. (Check all that apply)

Select all national surveillance systems where data from this outbreak were reported and list the corresponding reporting numbers if you know them. For outbreaks with a corresponding NORS report, please enter the NORS user assigned “State ID” and the CDC assigned “CDC ID.”

Select *Other* if the national surveillance system is not listed, then enter the official name of the system (not the abbreviation) in the description box.

10. Was a specific ingredient or multi-ingredient food suspected or confirmed in this outbreak?

This section should only be completed if a specific ingredient or multi-ingredient food has been implicated (either confirmed or suspected) in the outbreak.

If *Yes*, → (Complete Parts Va. and Vb. [Suspected/Confirmed Foods]) and → (skip to question 11)

If no specific ingredient or multi-ingredient food is implicated, select *No* for question 10.

In some instances, there are no (or no available) laboratory methods to identify an agent (for example, norovirus in food). In these cases, a confirmed food is characterized by isolation of the agent from ill persons and a statistical significance for a particular food eaten by those who are ill. For some toxins such as botulism and ciguatera, a statistical significance for a particular food eaten by those ill is adequate for a confirmed description.

Only complete this section if a specific food item (multi-ingredient food) or specific food ingredient has been implicated in the outbreak. To understand the difference between a specific food item and a specific food ingredient, consider the following examples:

Example 1: A hamburger sandwich is implicated but no specific food ingredient such as the ground meat, lettuce, or tomatoes was implicated. The hamburger sandwich is the implicated food item. In this case, the hamburger sandwich would be considered a multi-ingredient food.

Example 2: A hamburger sandwich may be implicated, but a specific ingredient of that sandwich such as lettuce was the specific food item implicated. Lettuce is the specific food ingredient implicated, and it would be described in the data collection instrument as a specific ingredient.

For additional guidance, please see Part V (Suspected/Confirmed Foods).

10a. If an ingredient/food was not suspected or confirmed: Explain why this outbreak was considered foodborne.

Explain why food is the suspected vehicle, but no specific ingredient or food item is identified. For example, in a norovirus outbreak a specific location may be identified and epidemiologically linked to food, but no specific food item or ingredient identified.

Foodborne illness outbreaks do not always have specific food items that were suspected and confirmed. There are many reasons for not being able to identify suspected or confirmed food items, such as:

- A food worker prepared many different foods in the establishment while ill and did not follow proper hygiene or glove precautions.
- Cleaning and/or sanitation practices maintained or promoted cross-contamination in the establishment.
- A contaminated food item was used in many foods served in the restaurant, but no epidemiological or laboratory data have provided information to narrow the suspected or confirmed food items.

Example: A deli establishment is involved in an outbreak. A sandwich made in the deli is the suspected food, but no specific sandwich was implicated.

The following guidance is only for individuals who also enter this outbreak into NORS.

When reporting this outbreak into NORS, check the box for food vehicle undetermined. An outbreak would be considered foodborne with an undetermined vehicle when information gathered in the investigation strongly suggests a common food as the source of infection, but a specific food vehicle is not identified. If a food vehicle is undetermined, enter the evidence that the outbreak was considered foodborne with an undetermined vehicle. The types of evidence used when reporting an implicated food to NORS are epidemiologic, laboratory, traceback and/or environmental investigation, and other. For descriptions of the types of evidence, refer to the [NORS Guidance](#) document.

11. Provide any comments that would help describe the foods involved in this outbreak.

Provide any comments that would help describe the foods involved in this outbreak that has not been captured in the standardized portion of this section.

12. Were any contributing factors identified in this outbreak?

- Select *Yes* if at least one contributing factor was identified in this outbreak. → (Complete Part VII [Contributing Factors])
- Select *No* if the foodborne illness outbreak investigation was not able to identify any specific contributing factors or if not enough evidence was found to support contributing factors in this outbreak.

Note: Not all foodborne illness outbreak investigations identify contributing factors.

For additional guidance, please see Part VII (Contributing Factors).

13. What activities were conducted during the outbreak investigation to try to identify the

contributing factors? (Check all that apply)

Identify all activities conducted during this foodborne illness outbreak investigation. Include all activities of the environmental health officers, communicable disease/epidemiology program, and laboratory program conducted to collect information about the outbreak.

Please document all relevant activities that occurred during the foodborne illness outbreak investigation beginning with the complaint that was received through the conclusion of the investigation. What activities were conducted to try to assess the reason that the outbreak occurred?

Examples of activities may include interviews with ill patrons, managers and food workers, food preparation review, and environment, food, and clinical sampling.

Select *Other* if the specific activity conducted is not listed, then enter the details of the activity in the description box.

Purpose of Question 14: The purpose of this question is to describe how the food safety program categorizes the quality of communication during the outbreak investigation. This question is meant to rate the communications as perceived by the program conducting the EA. There is no correct answer to this question.

14. Please rate the quality of communication between the food regulatory program and the communicable disease program during this outbreak investigation.

Rate how you feel the quality of communications between your program and other programs involved in this specific foodborne illness outbreak investigation was. This is just your estimate, and it doesn't need to be exact. This includes communication among all programs involved in the investigation (food safety, communicable disease/epidemiology, laboratory, and any others) about the suspected pathogen, food, and contributing factors.

15. What were the environmental antecedent(s) of this outbreak? (Check all that apply)

The CDC defines contributing factors and environmental antecedents as the following:

- **Contributing Factor(s)** – Contributing factors are the most likely factors to contribute to the contamination, survival, and/or proliferation of the etiologic agent or suspected agent. (Refer to Part VII [Contributing Factors] guidance for list of all contributing factors).
- **Environmental Antecedent(s)** – EAs are the conditions leading to the contamination, survival, or increase of biological or chemical agents in food. They may be related to people, equipment, food process, food type, economics, or other circumstances. In other words, EAs are the reason(s) why contributing factors occur.

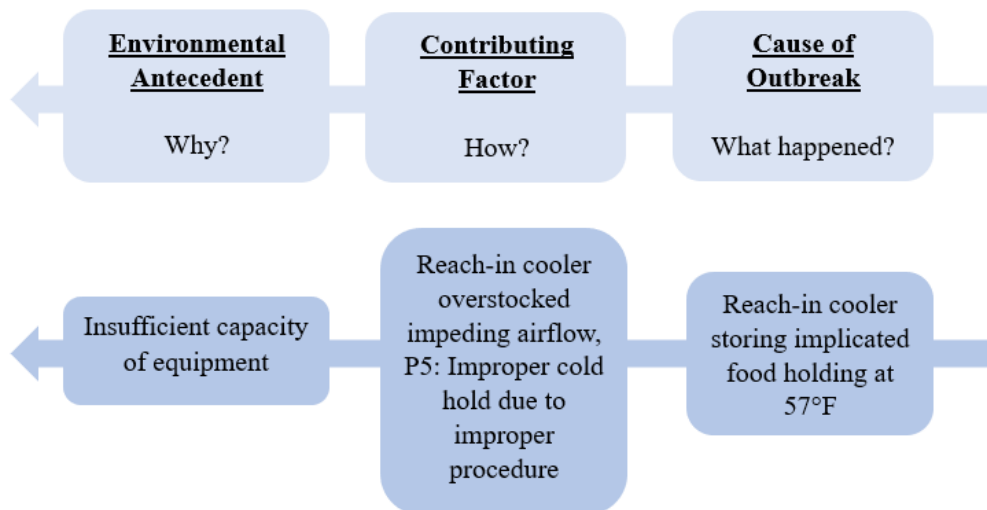


Figure 1. Relationship of Antecedent to Outbreak

The environmental antecedent and the contributing factor are related in an outbreak. Typically, the process starts with identification of an outbreak and the causative agent. Next, investigators try to figure out how the outbreak happened, leading to the identification and selection of a contributing factor. As investigators continue to work backwards to understand why the outbreak happened, they will identify the antecedents that allowed the contributing factor to occur.

Types of Environmental Antecedents: Internal System Variables of a Food Establishment

Researchers have theorized that there are five main groupings of factors in a restaurant that influence the restaurant's food safety. These five groups, or internal system variables, are: people, equipment, processes, foods, and economics (Higgins et. al, 2004). There may be more than one environmental antecedent and they may be associated with one or many of these internal system variables.

Internal system variables such as people, equipment, processes, foods, and economics can exert both positive and negative influences on food safety in food establishments. For example, a manager who ensures workers care about food safety would be a positive people influence, while a manager that doesn't train workers on food safety would be a negative people influence. See below for additional variable examples that can exert either positive or negative influence on a restaurant's food safety system.

People –employee health, hand washing, clothing, training, supervision, development of food safety plans and SOP's, implementation of procedures, pay, sick leave, etc.

Equipment –design, construction, cleanability, maintenance, placement of equipment, proper installation, etc.

Process –having a kill step, handling after a kill step, multiple steps in a food process, performing special processes (e.g., vacuum packaging), etc.

Foods –the source of the food, pH, water activity (a_w), viscosity, etc.

Economics –food trends, profit, operational costs (e.g., food costs, cost of equipment and facilities, staffing and training), etc.

Determining Environmental Antecedents

The goal of the EA is to identify the reasons that people are becoming ill and introduce control measures that stop the spread of illness. The contributing factors to an outbreak are typically the failures in the farm-to-fork continuum that enable the outbreak. Environmental antecedents are the conditions leading to the contributing factors. The environmental antecedents can be thought of as the root cause* of why the outbreak occurred, and the contributing factor can be thought of as a symptom of that root cause.

Determining environmental antecedent(s) can be challenging even when a contributing factor has been identified. However, to prevent another outbreak from occurring, identifying and eliminating the root cause of the contributing factor(s) is essential. Evidence obtained during both the EA and the outbreak investigation as a whole can help guide investigators in identifying the environmental antecedent(s). From the EA, investigators should consider the findings from interviews with managers and food workers, observations, record reviews, and the establishment's policies and practices (see Methods section on page 17). Outside of the EA, investigators should also consider all findings the epidemiological investigation and laboratory tests when determining environmental antecedent(s). The information in this section will provide guidance on how to systematically utilize all this data to identify the environmental antecedent(s) of an outbreak.

Environmental antecedents may not be obvious at first. Often, these factors are not covered by regulations and investigators need to use their knowledge, experience, and professional judgement to ascertain the antecedents to the outbreak. Because it takes a broad view of the entire outbreak and multiple perspectives, consider convening a meeting of the outbreak team to discuss investigation findings and identify environmental antecedents together.

***The term “root cause” can have varying meanings to different agencies. CDC uses the term to refer to the environmental antecedents of the outbreak, while other agencies may use it to refer to the contributing factor that resulted in the outbreak.**

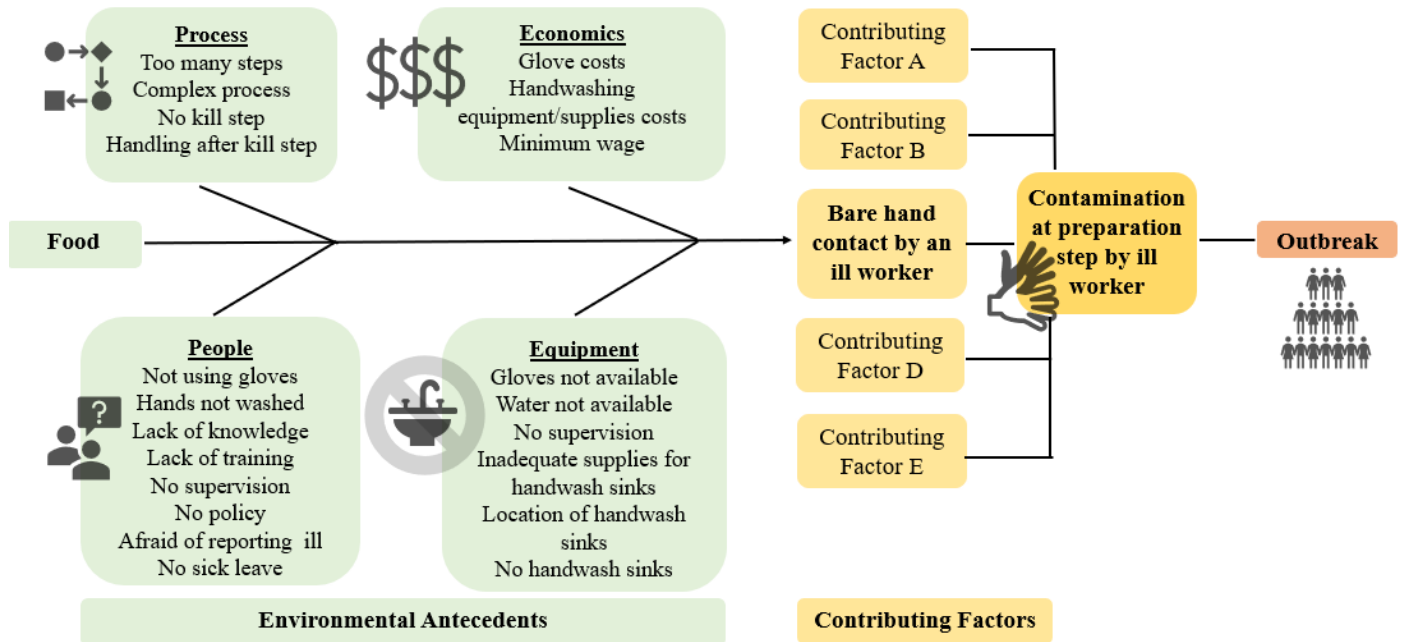


Figure 2. Relationship of Environmental Antecedent(s) to Contributing Factor(s)

In Figure 2, Contributing Factor C10 – Bare-hand contact by an infectious food worker was identified as the contributing factor. The investigation also identified several environmental antecedents that likely contributed to that bare hand contact, including inadequate training on employee health policy (which led to the worker working while sick), and lack of gloves (which prevented the worker from wearing them).

One method for gaining information on the cause of the outbreak and determining the environmental antecedents is to continue to ask “why?”. The five whys is an interrogative technique to determine the root cause of the issue and each question forms the basis of the next question (Serrat O. et al., 2017).

- *Example* (Refer to Figure 2): Why did the worker use their bare hands? Because there were no gloves in the restaurant. In that case, why were there no gloves? Because the manager stated they were too expensive. Continue down this path until you run out of questions or actions can no longer be taken to address the response.

Methods to utilize for environmental identification

During the outbreak investigation:

- Conduct interviews with managers to understand establishment’s policies and practices.
- Conduct interviews with food workers to determine information, such as: if workers are working while sick; their knowledge/training on specific food processes, equipment, or establishment practices/policies; the establishment’s food safety culture; etc.
- Review establishment’s practices and policies (written and verbal).

- Review the establishments records such as, temperature logs, sick worker logs, maintenance records, etc.
- Review establishments inspection history (*Use caution when reviewing prior inspection records as this may cite a practice that occurred in the past, which may not be true during the time of the outbreak, and ultimately may not relate to the cause of the outbreak*).
- Review data collected in NEARS instrument (i.e. Establishment Characteristics; Manager Interview; Observation; Sampling) to provide more information and link to environmental antecedent.
- Observe employee practices and food processes to identify trends that may have been present during the time of the exposure(s).
- Use the 5 whys to determine the outbreak cause, contributing factor(s), and environmental antecedent(s).

After the outbreak investigation:

- For each contributing factor, use the five why's method: ask why repeatedly until you get to the environmental antecedent.
- Meet with or consult the entire outbreak team to gain a broad perspective of the outbreak and to discuss potential environmental antecedents.
- Re-review all information collected during the investigation.

Examples of Environmental Antecedents

These examples are not all inclusive nor exhaustive but meant to provide investigators with some insight on how to use and interpret the identification and selection of environmental antecedents.

- **Lack of training of employees on specific processes** –Food workers are unfamiliar with how they are supposed to perform a process because they were not trained how to perform specific processes by the establishment/management.
Example: The establishment has a cooking procedure for a food item, but the worker was not trained on this procedure and is unsure of proper cooking temperatures or does not understand this is a critical control step to kill pathogens.
- **Lack of oversight of employees/enforcement of policies** – There is a lack of supervision or enforcement to ensure that policies or processes are being followed.
Example: Food workers are trained by an owner or manager when they are hired, but there is not typically a manager or supervisor present to ensure that the workers are following the proper procedures. In some cases, the manager may always be present, but does not provide adequate oversight to ensure workers are following proper procedures.
- **High turnover of employees or management** – There is a high turnover of food workers or management staff that results in people being unfamiliar with the establishment's processes and policies. High turnover may limit the amount of training and experience workers receive in food safety practices. This may also result in delayed or incomplete training for new workers.
Example: The turnover rate is so high that the establishment employees lack institutional knowledge to provide on-the-job training or there is a lack of training prior to having someone start working. This results in new workers not being familiar with the processes of the restaurant and may lead workers to practice unsafe food handling.

- **Low/insufficient staffing** – There are not enough food workers present to handle the workload. This could lead to workers taking shortcuts, multi-tasking, or performing unfamiliar food handling activities, which may negatively affect food safety. This could be assessed by reviewing the restaurant volume (i.e. number of meals served daily) and conducting observations to determine if the number of available food workers and managers are adequate to support the food operation.
Example: During the assessment an investigator visits an establishment and one food worker is trying to prepare, cook, and serve the food. Due to the large quantity of business and the number of tasks this worker is assigned, they take shortcuts (i.e. not washing hands or not cleaning/sanitizing surfaces) that lead to contamination of a product that causes illnesses.
- **Lack of a food safety culture/attitude towards food safety** – This may be represented by disregard for food safety practices. The employees may understand food safety but choose poor food safety practices out of convenience, or because they feel the risk of illness is low.
Example: The manager in the establishment knows the food safety requirement for cooking chicken livers is 165°F, but because they have been eating it their entire life undercooked and never got sick from it, the manager encourages their workers to undercook it. The investigator may find that this manager does not agree with many of the food safety requirements that are recommended and therefore the investigator deems that the establishment does not have a positive food safety culture.
- **Language barrier between management and employees** – This may be evidenced by management and workers speaking different languages and the manager is unable to communicate the processes that a worker should follow. Information in Part III (Manager Interview) may reveal some of this information.
Example: The establishment manager speaks language X and the food workers speak language Y and the manager is unable to explain the processes of the establishment due to the language barrier.
- **Insufficient capacity of equipment (not enough equipment for the processes)** – Equipment does not meet the requirements for the operation. This includes, but is not limited to, equipment related to temperature control, sanitation, and hygiene.
Example: The reach-in refrigerator was overloaded, and it blocked all the condenser vents so the cold air couldn't circulate. The investigator finds the temperature within the unit is running high and once all the stacked containers are removed from the reach-in unit, the ambient temperature goes down to 41°F. The establishment says it is their only refrigeration unit and that is why it is always so full.
- **Equipment is improperly used** – Equipment is not being used as intended or was not intended for use with food. This includes, but is not limited to, equipment related to temperature control, sanitation, and hygiene.
Example: When conducting the food flow, the investigator determines that soups are reheated in a hot holding unit. The hot holding unit does not get hot enough to reheat the soup to 165° F and it takes three hours to reach 135°F. The investigator informs the establishment that the hot

holding unit is not designed to reheat food, and they should reheat the soup using a conventional cooking device prior to putting it in the hot holding unit.

- **Lack of preventative maintenance on equipment** – Equipment is not routinely maintained and no longer functions as intended.
Example: A refrigeration unit was running at high temperatures and therefore allowed pathogen proliferation. When trying to determine the cause of the high temperatures, the manager reported to the investigator that the refrigeration unit had not undergone routine maintenance for a long time. In addition, the investigator observed soiled condenser fans/filters and the door gasket was missing on the refrigerator door. It was determined these were the reasons for the unit's high temperatures.
- **Poor facility layout** – The design of the facility inhibits safe food practices, such as cross-contamination.
Example: The raw meat preparation area was adjacent to the salad preparation area. During meat preparation, meat juices and debris splashed into the salad preparation area. The food worker responsible for salad preparation did not clean and sanitize the counter before preparation, which caused the meat juices to contaminate the ready-to-eat salads.
- **Lack of sick leave or other financial incentives to adhere to good employee health practices**– Workers reported that they work while sick because of financial restraints.
Example: Food workers have been working while symptomatic with vomiting and/or diarrhea. It is determined through interviews that the reason the workers worked while sick was because they could not afford to take time off work and the establishment does not offer paid sick time or the ability to make up hours when they return to work.
- **Lack of needed supplies for operating the restaurant**— An establishment runs out of basic supplies needed to operate the establishment.
Example: Food workers are observed contacting ready-to-eat foods with their bare hands and when interviewed, the food workers explain that the establishment frequently runs out of gloves.
- **Insufficient process to mitigate the hazard** – The process that the establishment is using to prepare food allows pathogens to survive and fails to control pathogens. The establishment may have believed that the process was sufficient, but never verified that the process works.
Example: An establishment has a specific process written down that cooks must cook the rotisserie chickens for 25 minutes at 350°F. All the cooks follow this process, but do not take temperatures for each batch. During the investigation, the investigator checks the temperature of the rotisserie chicken after 25 minutes, when the cooking timer goes off, and the internal temperatures for the larger chickens are less than 165°F. This process was therefore insufficient to eliminate the pathogens of concern for chicken.
- **Employees or managers are not following the facility's process** – The establishment has a process on how to perform the job task, but it is not being followed.
Example: An establishment has written procedures for how to properly clean up after a vomiting event. The investigator determines that a sick guest vomiting caused a norovirus

outbreak. The investigator asks if they have a policy and is provided with a policy that seems as though it would be effective against norovirus. When the investigator asks the manager to walk through how they cleaned it up, the manager tells the investigator they brought all the cleaning equipment such as the bucket and mop head into the dish area and sprayed it with the spray hose, which was adjacent to the clean dish rack, to clean it before they stored it away. The policy states that they have disposable mop heads that are discarded after they are used, but the establishment does not follow this practice. This shows that they do not follow their own process for cleaning.

- **Food not treated as time/temperature control for safety (TCS)**—The establishment staff does not handle food items that are TCS (or potentially hazardous food [PHF]), to control or prevent pathogens. These handling and preparation methods may contribute to pathogen survival and/or proliferation.

Example: An establishment staff member cans their own garlic stuffed cherry peppers made in oil and sells them as shelf-stable products. A *C. botulinum* outbreak occurs and upon investigation the lab testing determines that this product is not shelf-stable, and the establishment did not recognize the hazard. Other examples may include, but are not limited to: cut leafy greens, cut tomatoes, sprouts for smoothies, and cooked vegetables.

16. Briefly describe any other information about the underlying causes of the outbreak (ex: order of environmental antecedents).

Based on your professional training and experience and the information you gained from the outbreak investigation, please provide a short narrative of what was observed. There likely could be multiple antecedents that are interconnected. In this case, please list the order of which this happened due to A, which happened because of B, which was due to C.

For example, a norovirus outbreak had a primary contributing factor of an ill food worker. The antecedents to this outbreak would focus on why the worker was working while ill and may include: the worker would not get paid if he didn't work, his manager made him work because he could find no one to replace him or other reasons. It may be helpful to think of environmental antecedents in terms of people, equipment, food process, food type, or financial.

17. Were any control measures implemented for this outbreak?

Control measures are actions or activities that are taken to prevent, eliminate, or reduce the occurrence of a hazard that has been identified. Control measures are critical for stopping an outbreak and preventing reoccurrence at a specific location. If *No*, → (skip to Part II [Establishment Description, Categorization, and Menu Review])

17a. If control measures were implemented, what were they? (Check all that apply)

Please indicate the control measures implemented for this outbreak, based on your professional training and experience.

Once the food source of an outbreak is determined, control measures must be taken. If contaminated food stays on store shelves, in restaurant kitchens, or home pantries, more people may get sick. Several different outbreak control measures can be taken. Public health officials

choose measures based on the information available to them. Measures can change as the investigation goes on. Examples of outbreak control measures include:

- Cleaning and disinfecting food facilities
- Temporarily closing a restaurant or processing plant
- Recalling food items
- Telling the public how to make the food safe (such as cooking to a specific temperature) or to avoid it completely

Public health officials may decide on control measures based on strong epidemiological evidence of the disease's origin, spread, and development. They do not need to wait for proof of contamination from the laboratory. This practice can result in earlier action to protect the public's health. As officials learn more during the investigation, they may change, focus, or expand control measures and advice to the public.

For more information, please see the Council to Improve Foodborne Outbreak Response (CIFOR) guidelines (<https://cifor.us/downloads/clearinghouse/CIFOR-Guidelines-Complete-third-Ed.-FINAL.pdf>).

Part II: Establishment Description, Categorization, and Menu Review

Purpose of Part II: Part II gathers basic information about the establishment's menu, food offered, and potential language barriers. It identifies establishments where a translator was needed or used to communicate with the manager. Information gathered in this section will be based on the menu review and initial discussion with the manager.

General Instructions for Part II: Question 1 refers to the date the establishment was identified for an environmental assessment (EA)(or became a suspect establishment); question 2 refers to the date the first contact was made with the establishment (by the environmental health/food program). Part III (Manager Interview), question 2 and Part IV (Establishment Observation), question 2 refer to the date the manager was first interviewed, and when the observation of the establishment was conducted, respectively. These four dates may be the same day, or they may be on different days. It is preferable to complete the interview and observation on the date of the first contact, but that might not be possible. Information gleaned from the initial years of NEARS supports that performing the EA sooner leads to a higher probability of identifying the contributing factors. The timeline of an outbreak investigation is essential. It helps in reconstructing events and understanding strengths and weaknesses in outbreak response.

1. Date the establishment was identified for an environmental assessment.

Enter the date (MM/DD/YYYY) the establishment was identified for an EA. The establishment may have been identified by any member of the foodborne illness outbreak response team (laboratory, communicable disease control, and regulatory program).

Team members might suspect that an establishment is part of the outbreak for some time before a decision is made to conduct an EA. This date only refers to the date the decision was made to conduct an EA. It may or may not be the same as dates in Part II (Establishment Description), question 2; Part III (Manager Interview), question 1; or Part IV (Establishment Observation), question 1.

2. Date of the first contact with establishment management.

Enter the date (MM/DD/YYYY) of the first contact with the establishment's management (a responsible party such as owner, manager, head chef, etc.) by the environmental health/food program. This contact may have been a phone call or visit to the establishment.

Although it is preferable to complete the manager interview on the date of the first contact, this may not be possible. This date only refers to the date of the first contact. It may or may not be the same as the date in Part II (Establishment Description), question 1; Part III (Manager Interview), question 2; or Part IV (Establishment Observation), question 2.

Purpose of Questions 3 and 4: An EA does not have a specific number of visits and communications in a particular establishment. Each EA is different and depends on the outbreak and the establishment. This question helps describe the time and resources required for this EA and provides your jurisdiction with estimates about the time dedicated to outbreak response.

3. Number of visits to the establishment to complete this environmental assessment.

Enter the number of times the establishment was visited by an environmental health specialist or member of the outbreak team to complete the EA. This includes visits to interview the manager, observe food preparation, collect food flow information, and review and collect records. If you do not know the exact number of visits, please estimate.

4. Number of contacts with the establishment other than visits (for example, phone calls, phone interviews with staff, faxes, etc.) to complete this environmental assessment.

Enter the number of times this establishment was contacted to complete the EA. This includes communication made before or after the actual physical visit(s) as long as the communication was part of conducting the EA. Forms of contact may include phone calls, interviews conducted over the phone with a manager, gathering information and records about ingredients/foods, etc. If you do not know the exact number of contacts or communications, please estimate.

5. Facility Type.

Indicate the type of facility where the EA was conducted. Review the list of facility types carefully. Select the type that most closely matches the type of facility where this EA took place. If the type does not closely match anything listed, select *Other* and describe the type of facility as clearly as possible.

This instrument was developed specifically to report information from EAs that take place at the point of final preparation or service. For EAs that take place at facilities such as commissaries or other facility types where foods are prepared for final service, select *Other* for facility type and complete all sections of the instrument. For facilities such as processors, manufacturers, farms, etc. select *Other* and describe. Complete all sections of the instrument except Part III (Manager Interview).

Please contact the CDC staff if you have any questions about how to categorize a facility or what sections of the instrument should be answered. Specific questions about other facility types where EAs are conducted will be developed in the future.

6. How many critical violations were noted during the last routine inspection?

Review the files and the last **routine** inspection report before the outbreak under investigation. Report the number of critical/priority/priority foundation violations noted on the last **routine** inspection.

For this data collection, critical violations are those that are more likely to contribute to the contamination of food, proliferation of pathogens, toxins, or other hazards and survival of the pathogens if the violations are not corrected. Examples include improper cooking, cooling, and holding temperatures of foods; opportunities for cross-contamination; poor hygienic practices; working while ill, etc. These data provide information about risk factors that may have existed before the current outbreak occurred.

Violations related to dirty floors, floor drains, areas in the facility in need of repair, lack of hair restraints, or similar violations are not considered critical for this data collection.

Please contact CDC staff if you have any questions.

6a. If critical violations were noted: Mark any of the following observed during the last routine inspection.

1. Improper hot/cold holding temperatures of foods (time/temperature control for safety [TCS]/ potentially hazardous food [PHF])

2. Improper cooking temperatures of food
3. Soiled or contaminated utensils and equipment
4. Poor employee health and hygiene
5. Food from unsafe sources
6. Other

A TCS food/PHF is one that requires time and temperature controls to limit pathogenic microorganism growth or toxin formation.

Purpose of Questions 7, 7a, 8, and 8a: This information identifies EAs where the evaluator was unable to communicate with managers and food workers confidently. The term *Needed* refers to what the evaluator **feels** was required to be able to communicate with managers effectively.

7. Was a translator needed to communicate with the kitchen manager during the environmental assessment?

- Select *Yes* if a manager does not speak English or speaks English as a second language and the evaluator feels questions being asked are not completely understood due to a language barrier **or** if questions seem to be understood. Still, the response cannot be understood by the evaluator. This includes multilingual evaluators who can communicate with the manager in their primary language.
- Select *No* if a manager speaks English or English as a second language and the evaluator can ask questions, feels the questions are understood. The evaluator can understand the responses to the questions asked. → (skip to question 8)

This question refers to the entire EA, including the manager interview. This answer is based on contact and interaction with the manager in charge of the kitchen.

7a. If a translator was needed: Was a translator used to communicate with the kitchen manager?

- Select *Yes* if the evaluator used translator services or if the evaluator is multilingual and was able to communicate with the kitchen manager in the kitchen manager's primary language.
- Select *No* if a translator was not used.

8. Was a translator needed to communicate with the food workers during the environmental assessment?

- Select *Yes* if the food workers do not speak English or speak English as a second language and the evaluator feels questions being asked are not completely understood due to a language barrier **or** if questions seem to be understood. Still, the response cannot be understood by the evaluator. This includes multilingual evaluators who can communicate with the food workers in their primary language.
- Select *No* if the food workers speak English or English as a second language and the evaluator can ask questions, feels the questions are understood, and the evaluator can understand the responses to questions asked. → (skip to question 9)

This question refers to the entire EA. The answer is based on contact and interaction with the food workers.

8a. *If a translator was needed:* Was a translator used to communicate with the food workers?

- Select *Yes* if the evaluator used a translator or if the evaluator is multilingual and was able to communicate with the food workers in the food workers' primary language.
- Select *No* if a translator was not used.

General Instructions for Questions 9-12: The evaluator should answer the following questions after discussing the menu with the kitchen manager and conducting a menu review.

9. Establishment Type.

To determine the establishment type, you need to review the menu. Do not make assumptions about the ingredients used or the process used to prepare them. For data collection for this tool, use the definitions below to classify the establishment type regardless of how your jurisdiction classifies them. After reviewing the menu, determine the establishment type using the most complicated process that occurs in this establishment and using the following definitions:

- *Prep-Serve:* An establishment where all food items are prepared and served without a kill step. Some food on the menu may be commercially prepared ready-to-eat food that may be heated for service without a kill step.
- *Cook-Serve:* An establishment where at least one food item is prepared for same-day service and involves a kill step. The menu may also include prep serve items or have some food on the menu that is commercially prepared and heated for service.
- *Complex:* An establishment where at least one food item requires a kill step and holding beyond same-day service or a kill step and some combination of holding, cooling, reheating, and freezing. The menu may also include any combination of prep-serve, cook-serve, and complex food items.

10. Do customers have direct access to unpackaged food such as on a buffet line or salad bar in this establishment?

- Select *Yes* if customers have direct access to unpackaged food.
- Select *No* if customers do not have direct access to unpacked food.

This question does not refer to self-service soda areas where customers dispense their ice and soda from self-service machines and do not have direct contact with the beverage or ice others use.

Example: A customer is given a beverage cup and fills the cup with ice and beverage from dispensing machines that do not allow the customer to come in direct contact with the ice or beverage being dispensed. If this is customers' only access to unpackaged food, answer this question *No*.

Purpose of Questions 11, 11a, and 11a1: This information helps determine whether a consumer advisory is provided in some form in establishments that serve raw or undercooked products. It also helps determine how those advisories are provided.

Consumption of raw or undercooked animal products is considered risky behavior. The U.S. Food and Drug Administration (FDA) recommends that establishments that serve undercooked animal products make available a consumer advisory on these products. The FDA Food Code suggests the advisory be provided either as part of the menu or as a footnote.

The purpose of this section is to:

- determine if the establishment serves raw or undercooked animal products,
- determine if there is a need for a consumer advisory, and
- describe consumer advisories, the type of establishments that use consumer advisories, and the prevalence of advisories in outbreak establishments linked to undercooked animal products.

11. Does the establishment serve raw or undercooked animal products (for example, raw oysters or raw shell eggs) in any menu item?

- Select *Yes* if raw or undercooked animal products are served in any menu item. Be careful to clarify with the kitchen manager if eggs, hamburgers, etc. are served undercooked under any circumstances—such as at the customer's request.
- Select *No* if raw or undercooked animal products are NOT served in any menu item under any circumstances. → (skip to question 12)

11a. If establishment serves raw or undercook animal products: Is a consumer advisory regarding the risk of consuming raw or undercooked animal products provided (for example, on the menu, on a sign)?

- Select *Yes* if there is a written statement anywhere informing consumers of the risk of consuming raw or undercooked animal products. The advisory does not need to meet the FDA Food Code requirements, but at least have an attempt at meeting the advisory requirement.
- Select *No* if there is no written statement anywhere informing consumers of the risk of consuming raw or undercooked animal products. → (skip to question 12)

Look at the menu carefully. A consumer advisory may be in small print.

11a1. If the establishment serves raw or undercooked animal products and has an advisory: Where is the consumer advisory located? (Check all that apply)

Identify all places a consumer advisory is located. Select the answer choice that most closely fits the locations identified. Review the answer choice carefully. It is crucial for accurate data analysis that you select from the list provided if one of the choices best describes the location(s).

If a location type is not listed, select *Other* and describe the type as clearly as possible. Clearly describe why this location does not fit into the categories provided.

Purpose of Question 12: Data suggest, certain cuisines have been associated with a higher number of foodborne illness complaints. The purpose of this question is to collect descriptive data on the establishment menu type to understand how menu type may correlate with illness outbreaks.

12. Which one of the options below best describes the menu for this establishment?

Review the list of menu descriptions carefully and select the option that best fits the overall menu theme. If you choose *Other*, please describe the type of menu in the space provided. For instance, select *Other* if the menu is multiethnic, such as Chinese/Italian/American.

Example: A Chinese menu might include a few items for children, such as a grilled cheese sandwich or hamburger sandwich, but the menu theme is Chinese. Select *Chinese*.

Purpose of Question 13, 13a, and 13b

The purpose of these questions is to collect information on any environmental sampling conducted during the foodborne illness outbreak investigation. For NEARS, reported sampling includes **only environmental sampling** (either food or environmental surface sampling); it does not include clinical samples, such as vomit or feces samples. It should include all samples taken as a part of the EA, including presence/absence, detect/non-detect, or specific value (e.g., X ppm or X cfu/g) samples.

Use the section titled Collect Samples of Suspect Food in the International Association for Food Protection (IAFP) *Procedures to Investigate a Foodborne Outbreak Investigation, Sixth Edition* (pages 41-44) as a general guide for collecting food samples. Additionally, you should use your jurisdictional guidance/instructions as guidance for food sample collection.

Each person collecting the samples should follow their jurisdictional instructions for the food and environmental samples collected.

For additional guidance, please see Part VI (Positive Samples).

13. Were any samples taken in this establishment?

- Select *Yes* if at least one food or environmental sample was collected in the establishment as part of the EA. If any samples were positive, complete Part VI (Positive Samples).
- Select *No* if no environmental samples were taken. → (skip to Part III [Manager Interview])

13a. If environmental samples were collected: Where were they taken? (Check all locations that apply and enter the number of samples taken at each location)

Check the box(es) that most closely corresponds with where the environmental sample(s) was (were) taken in the establishment. If none of the answer choices are appropriate, select *Other* and concisely describe the location where this sample was taken.

Provide the total number of environmental samples collected and processed from each location during the EA in this establishment.

13b. If food samples were taken: What foods or ingredients were sampled? (Check all that apply and enter the number of samples taken of each food)

Check the box(es) that most closely corresponds with where the environmental sample(s) was (were) taken in the establishment. Provide the name of the specific food sampled for specific food ingredients and multi-ingredient food. The name(s) given in this section for positive samples should match the specific food name(s) given in Part VI (Positive Samples).

Part III: Manager Interview

Purpose of Part III: To characterize the policies and practices in the establishment based on a manager interview.

General Instructions for Part III: These questions should be asked of an establishment manager with authority over the kitchen (Kitchen Manager). The interview may be conducted on the initial face-to-face or phone contact with the establishment manager, if practical. This section should be completed as early in the investigation process as possible (preferably within 24-48 hours of the establishment being identified for an environmental assessment [EA]). During the outbreak investigation there may be interviews with multiple managers. For the purpose of this manager interview, it should reflect an interview with the manager that has the most authority over the kitchen AND is most familiar with the day-to-day operations of the kitchen.

The interview format is intended to be used as a semi-structured interview. The form should be used as an interview guide, with a list of questions and topics that should be covered during the interview. However, if answers to questions yield intriguing responses, these should be followed up with open-ended probing questions. The interviewer can rephrase or clarify questions if the question is unclear so manager can better understand what is being asked.

Additional instructions for some questions are provided in boxes. Read aloud all boxed text throughout the interview; this information is marked READ ALOUD.

Do not read answer choices aloud unless specifically noted using bold text. **Do not** read the *Unsure* or *Refused* answer choices.

Remember, manager responses may or may not match with the regulatory requirements for your jurisdiction. Record the manager's responses regardless of whether or not they are appropriate based on the regulatory requirements for your jurisdiction.

In some food establishments, English may be a second language for the kitchen manager. If you responded *Yes* to Part II (Establishment Description), question 7 (Was a translator needed to communicate with the kitchen manager?), it may still be difficult to conduct this interview depending on the translator's skill.

You should make every effort to answer these questions based on the kitchen manager's responses to the questions, **NOT** on your assumptions. If the manager

- refuses to answer a question, indicate the response as *Refused*.
- is unsure of the answer, indicate the response as *Unsure*.

If you are not able to get an answer to a question based on poor communication, do not make an answer selection; skip the question.

Establishment—General

1. How long was the interview(s)?

Track the time you began the interview with the kitchen manager and the time you complete the interview. Record how many total minutes it took from start to finish. If the interview isn't completed in one sitting, add the times for the multiple attempts (to complete interview) together. This is to assess the burden of time needed to complete interview.

2. Date the manager interview was initiated (MM/DD/YYYY):

Enter the date (MM/DD/YYYY) that the interview was conducted. This date may or may not be the same date those in Part II (Establishment Description), questions 1 and 2.

Read the following aloud for managers:

READ ALOUD:

I'd like to ask you some questions about this establishment. Please be as open and honest as possible. The first few questions focus on the establishment in general. Please make your best estimate if you do not know the exact number for the following questions.

Purpose of Question 3: This question collects descriptive data on the establishment characteristic of ownership (chain vs. independent), a characteristic that may be associated with foodborne illness outbreaks. The assumption is establishments that are a part of some sort of chain are more likely to have the resources to have standardized processes, established training for managers and food workers, and, in some instances, the level of quality assurance programs that have worked to engineer out many of the hazards in their operations.

3. Is this an independent establishment or a chain establishment?

- Select *Independent*, *Chain*, *Unsure*, or *Refused* based on the manager's response.

An independent establishment has a unique name and operations. A chain establishment shares both name and operations with other establishments. Ownership of a chain establishment may be private, franchise, or corporate.

Purpose of Question 4 and 5: This question is an indicator of how busy the establishment is.

4. Approximately how many meals are served here daily? Meals can be estimated using number of customers served or ticket orders.

Record the approximate number of meals served at this establishment daily. If the manager refuses to answer, select *Refused*.

Number of meals served should be a daily average of meals from a 7-day period. Meals may be represented by ticket orders and/or customers served. Discuss with the operator about how some days are going to be busier than other day (e.g. weekends) but on average, how many meals are served daily when you look at the whole 7-day period.

5. What is the establishment's busiest day, in terms of number of meals served? (*Select one*)

Based on the manager's response, only select ONE day. If the manager responds that two or more days are the busiest days, reframe the question to ask if the manager had to choose just one day as the busiest, which would it be?

Purpose of Question 6: It is thought that establishments with off-premises preparation may be more likely to be involved in an outbreak. The purpose of this question is to collect descriptive data on the use of off-premises preparation. Examples of this situation include some restaurants where bakery items or desserts are brought in from another location or some mobile food vendors who purchase hot entrees from a commissary for resale.

6. Are any foods prepared or partially prepared at a commissary or any other location?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

Purpose of Question 7: Menu changes are thought to be an antecedent to outbreak events. The purpose of this question is to collect descriptive data on the establishment characteristic of recent menu changes, a characteristic that may be associated with foodborne illness outbreaks.

7. Other than daily specials, when was the last time food items were added to your menu(s)?

Listen to the manager's response and select the option that best defines the last time any food items were added to the establishment's menu other than daily specials.

Questions about the Kitchen Managers

Read the following aloud for managers:

READ ALOUD:

The next few questions focus on kitchen managers. As I read the following questions, please keep in mind that we are asking about managers who have control over the kitchen area or back of the house.

Purpose of Questions 8-15: Questions 8-15 are designed to collect descriptive data on several establishment management characteristics that may be associated with foodborne illness outbreaks, including language barriers, (lack of) manager experience, training, certification, and sick leave. These questions refer to the manager being interviewed and any other managers who have control over the kitchen. If there is only one kitchen manager with control over the kitchen, questions can be directed to that kitchen manager specifically.

Ask managers to make their best estimate if they do not know the exact number for these questions. For questions that ask about numbers, if the manager is not sure or if the number varies due to staff changes, ask the manager to guess about how many/how long on average.

8. Approximately how long have you been employed as a kitchen manager in this establishment?

Record the approximate length of time that the kitchen manager has been employed at this establishment.

If the manager refuses to answer the question, select *Refused*.

9. Approximately how long have you worked as a kitchen manager?

This question refers to the total amount of time the interviewee has worked as a kitchen manager. The response should include the time the person has worked as a kitchen manager at the current establishment and any other food service establishments before the current one.

If the manager refuses to answer the question, select *Refused*.

10. How many kitchen managers, including you, are currently employed in this establishment? If you aren't sure, use your best guess.

Record the total number of kitchen managers employed at this establishment. Include the manager being interviewed.

If the manager is unsure, ask if he or she could make an approximation. If the manager is still unsure, select *Unsure*; if the manager refuses to answer, select *Refused*.

Purpose of Questions 11-13: It is thought that language may be a barrier to food workers learning and implementing proper practices and policies. The purpose of these questions is to collect descriptive data on management's language abilities to help understand establishment characteristics that could be related to language barriers, a characteristic that may be associated with foodborne illness outbreaks.

Questions 11 and 12 describe all the language abilities of managers. For these questions, ability to speak a language fluently is defined as the ability for the manager to speak and understand the specified language smoothly, easily, or readily. For instance, a manager being interviewed may speak English, but is also able to fluently communicate in Spanish.

Read the following aloud for managers:

READ ALOUD:

The next few questions focus on the language-related knowledge and skills of all kitchen managers in your establishment. Please think about your language abilities and those of other kitchen managers in this establishment.

For the purpose of these questions, fluent means able to clearly, easily, and readily understand and communicate verbal messages in the language specified. If a manager is bilingual or trilingual, please indicate all languages he or she speaks fluently.

Please make your best estimate if you do not know the exact answer for the following questions.

Purpose of Question 11: The purpose of this question is to identify all the languages that managers in the establishment are able to fluently communicate in. Language barriers are thought to be an antecedent to foodborne illness because understanding tasks, protocols, and on-the-job training are basic for food safety.

**11. What language(s) do you and other managers in this establishment speak fluently?
(Check all that apply)**

Select all languages that any manager in the establishment fluently communicates in. The answers should reflect all managers who work directly in on-the-job training or supervising food workers. This question is intended to reflect the languages the manager knows other managers are fluent in because they speak or use the language at work. It is not assumed that the manager will know all languages for

which all managers are fluent. Please record all languages that the manager is able to identify.

Example: If a manager speaks to other managers in English but is known to speak to food workers regularly in Spanish, select *English* and *Spanish*.

Purpose of Question 12: The purpose of this question is to identify all the languages that managers have basic knowledge to communicate in and understand.

12. What languages do you and other managers speak at work? (*Check all that apply*)

Select all languages that managers speak at work. Managers DO NOT need to be fluent in these languages, but if they use this language at work to communicate with other managers and food workers, select the appropriate language.

Example: A manager may not be fluent in Spanish but uses some Spanish to communicate with food workers while at work.

Purpose of Questions 13-15: It is thought that establishments with trained/certified managers are more likely to implement prevention measures more consistently than their untrained counterparts and that these establishments are less likely to be involved in an outbreak. The purpose of these questions is to collect descriptive data on the establishment characteristics of manager training and certification—characteristics that may be associated with foodborne illness outbreaks.

For the purpose of these questions, on-the-job training refers to any sort of training conducted by the establishment or corporate office. That might be anything from posting material on the wall to viewing videos to computer-based training or to sending employees to a corporate kitchen for training.

A class or course refers to any training conducted by someone other than the establishment or corporate office—for example, by a university, community college, culinary school, health department, or similar entity.

A course of class from an American National Standards Institute (ANSI)-accredited program only should be selected if managers took the exam for the Certified Food Protection Manager certification.

If the manager is unsure of the exact numbers for these questions, please ask him or her to make their best estimate.

Read the following aloud for managers:

READ ALOUD:

The next few questions ask about kitchen manager food safety training and certification.

13. Do any kitchen managers receive food safety training?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If the manager says *No*, *Unsure*, or *Refused*, → (skip to question 14)

Training can be a course or a class, or it can be training that occurs on-the-job. The training referred to in this question is specific to food safety and would include things like proper cooking temperatures

and how to avoid cross-contamination by separately raw and ready-to-eat items. The training would not include discussion of specific recipes or production methods specific to the restaurant.

13a. How many kitchen managers have had food safety training? If you aren't sure, use your best guess.

Record the total number of kitchen managers at this establishment who have food safety training as described in question 13. This training does not have to include a certificate upon completion of training.

If the manager is unsure, select *Unsure*; if the manager refuses to answer, select *Refused*.

13b. What type of food safety training do kitchen managers (you) receive? Is it on-the-job, a class or a course, or a class or course from an ANSI-accredited program, such as ServSafe? (Check all that apply)

Record the answer(s) that corresponds to the manager's response. Be prepared to ask probing questions if it was a course to obtain details on whether or not it was a course offered through an educational institution or a course/class from an ANSI-accredited program. If the ANSI-accredited program option is selected, this means that the manager took an exam.

Read the following aloud for managers:

READ ALOUD:

The next few questions ask about kitchen manager food safety certification where you receive a certificate upon completion of the training course.

14. Are any kitchen managers, including you, food safety certified?

- Select *Yes* if at least one kitchen manager is food safety certified.
- If *No*, *Unsure*, or *Refused*, → (skip to question 15)

Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

Food safety certified/certification means the person possesses a document or paper that indicates he or she received training and/or passed an exam on food safety. This includes any formal food safety training where participants received a certificate upon completion of the training. For the purpose of this question, certification may or may not be through an ANSI recognized certification program such as ServSafe, National Registry of Food Safety Professionals, Prometric, or 360Training.

14a. 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, Prometric, or 360Training?

Record the number of managers who have been food safety certified through any ANSI-accredited program. If none of the managers are certified through an accredited program, record 0. Ask the manager to make his or her best estimate if they do not know the exact number for this question.

14b. How often is a certified kitchen manager present during hours of operation? Is it all of the time, most of the time, some of the time, rarely, or none of the time?

Read the answer choices to the manager and select the answers the manager provides. This is just their estimate and it doesn't need to be exact.

15. Does this establishment require that kitchen managers have a food safety certification?

Based on the manager's response, select *Yes*, *No*, *Unsure*, or *Refused*.

Some establishments may have a policy that requires managers to be food safety certified in order to be in a management position. Keep in mind that although a facility may have a policy requiring certification, it is possible that none of the current managers are certified.

[See explanation of food safety certified/certification in question 14.]

Questions about Food Workers

Purpose of Questions 16-16c2: These questions mirror the manager questions and are used to gather basic data about the food workers in an establishment. These questions quantify the number of workers in this establishment, identify the different languages spoken, and identify the types of training and certification for workers.

Read the following aloud for managers:

READ ALOUD:

The next set of questions focuses on food workers. By food workers I mean employees, excluding managers, who work in the kitchen.

This does not include staff who have no food handling responsibilities or who have very limited food contact such as adding garnish or condiments to a plate.

16. How many food workers do you have? If you do not know the exact number, an estimate will be fine.

Record the total number of food workers employed at this establishment.

If there are no food workers or all food workers are also managers and have been accounted for under the Kitchen Manager section, → (skip to question 17)

If the manager is unsure or refuses to answer the question, select *Unsure* or *Refused*.

General Instructions for Questions 16a and 16b: Questions 16a and 16b describe the languages that food workers speak and use at work to communicate with management and other food workers. For this question, ability to speak a language fluently is defined as the ability for the food worker to communicate (speak and understand) in the specified language smoothly, easily, or readily. It is not assumed that a manager will be knowledgeable about every language a food worker may be fluent in, but for these questions we focus on the languages people use in work-related activities and on understanding the general language abilities that all food workers use in the establishment.

Example: A food worker might speak English and French at work with other managers and employees but may also be fluent in Italian. For the purpose of these questions, record all languages you know

people in your establishment speak and understand fluently.

Purpose of Question 16a: The purpose of this question is to identify all the languages that food workers in the establishment are able to fluently communicate in. Language barriers are thought to be an antecedent to foodborne illness because understanding tasks, protocols, and on-the-job training are basic for food safety.

16a. What language(s) do food workers in this establishment speak fluently?

Select all languages that any food worker in the establishment uses to communicate fluently at work. Answers should reflect all food workers. Record all languages the manager can identify.

This question is intended to reflect languages the management knows workers are fluent in because they use those languages at work. It is not assumed that the manager will know all languages that all food workers are fluent in.

Example: The manager speaks to all employees in English, but the manager is aware that the food workers speak to each other regularly in Spanish and Spanish is the first language of many employees. Select *English* and *Spanish*.

Purpose of Question 16b: The purpose of this question is to identify all languages that food workers have basic knowledge to communicate in and understand.

16b. What languages do food workers speak at work?

Select all languages that food workers speak at work. Food workers do not need to be fluent in these languages, but if they use this language at work to speak to other managers and food safety workers, select the appropriate box.

Example: A food worker may speak Chinese at home and away from work but speaks basic English at work to communicate with management and Chinese when speaking with other food workers. Select *English* and *Chinese*.

Purpose of Questions 16c, 16c1, and 16c2: These questions refer to food workers and mirror the manager questions concerning training. It is thought that having both trained managers and workers would reduce the likelihood that establishments would be involved in an outbreak. The purpose of these questions is to collect descriptive data on the establishment characteristic of worker training, a characteristic that may be associated with foodborne illness outbreaks.

For the purpose of these questions, on-the-job training refers to any sort of training conducted by the establishment or corporate office. It might entail anything from posting material on the wall to viewing videos to computer-based training to sending employees to a corporate kitchen for training. A class or course refers to any training conducted by someone other than the establishment or corporate office—for example, by a university, community college, culinary school, health department, or similar entity.

Read the following aloud for managers:

READ ALOUD:

The next few questions focus on food safety training and certification among food workers, excluding managers, and food worker sick leave policies.

16c. Do any food workers receive food safety training? This training can be a course or a class, or it can be training that occurs on the job.

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → (skip to question 17)

16c1. How many food workers have had food safety training?

Record the total number of food workers at this establishment who receive food safety training. If the manager is unsure, select *Unsure*; if the manager refuses to answer the question, select *Refused*.

16c2. What type of food safety training do food workers receive? Is it on-the-job, a class or a course, or a class or course from an ANSI-accredited program, such as ServSafe? It could be any or all of these. (Check all that apply)

Record the answer(s) that corresponds to the manager's response. Be prepared to ask probing questions if it was a course to obtain details on whether or not it was a course offered through an educational institution or a course/class that leads to taking an exam from an ANSI-accredited program.

Questions about the Establishment's Cleaning Policies

Purpose of Questions 17-21: These questions focus on establishment policies. Food safety policies can be informal and part of on-the-job or other establishment training or they may be formal written documents that state the policy. It is thought that policies or schedules represent a purposeful food safety effort that may affect the likelihood of an establishment being involved in an outbreak.

The purpose of these questions is to collect descriptive data on the establishment characteristics of a variety of policies and schedules, characteristics that may be associated with foodborne illness outbreaks.

If the policy is written, or a schedule is posted for completing the activity, or there is a log to record that the activity in the policy was followed select the written response as *Yes*.

Read the following aloud for managers:

READ ALOUD:

Now I'm going to ask you some questions about policies you have in this establishment. Food safety policies can be verbal and part of on-the-job or other establishment training or they may be written documents that state the policy.

17a. Does this establishment have a cleaning policy or schedule for the cutting boards?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

17b. Does this establishment have a cleaning policy or schedule for food slicers?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

17c. Does this establishment have a cleaning policy or schedule for food preparation tables?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

17d. Does this establishment have a cleaning policy or schedule for frequently touched customer surfaces like menus, tables, and condiments?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If all the answers to 17a-17d are *No*, → (skip to question 18)

17e. If they have any of these policies: Are any of these policies written?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → (skip to question 18)

e1. Which ones? (Check all that apply)

Check the boxes to the corresponding policies based on the manager's response.

18. Does this establishment have a policy concerning disposable glove use?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → (skip to question 19)

18a. If there is a glove use policy: Does the glove use policy require that food workers wear gloves:**a1. When they have cuts or other injuries?**

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

a2. When handling ready-to-eat foods?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

a3. When handling raw meat or poultry?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

a4. At all times while working in the kitchen?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

18b. If there is a glove policy: Is this policy written?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

19. Does this establishment have a policy for cleaning up after someone has vomited or had diarrhea in the establishment?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

19a. Is this policy written?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

Questions about Food Temperature Policies

Purpose of Questions 20-21: These questions focus on policies about food temperatures in the establishment. It is thought that policies or schedules represent a purposeful food safety effort that may affect the likelihood of an establishment being involved in an outbreak. The purpose of these questions is to collect descriptive data on the establishment characteristics related to food temperatures—characteristics that may be associated with foodborne illness outbreaks.

Read the following aloud for managers:

READ ALOUD:

The next few questions refer to actual food temperatures, not the ambient temperatures where food is stored. The questions refer to temperatures taken using some type of thermometer.

20. Does this establishment have a policy to take the temperature of any incoming food products?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

This question only refers to receipt of time/temperature control for safety (TCS) foods/potentially hazardous foods (PHF).

21. Excluding incoming products, does this establishment have a policy to take food temperatures?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

This question only refers to TCS foods/PHF.

Questions about Employee Health Policies

Read the following aloud for managers:

READ ALOUD:

Now I'd like to ask you a few questions about worker health policies. Again, I am asking about policies that apply to staff who primarily work with food—not staff who have no or very limited food handling responsibilities.

Purpose of Questions 22-27: The purpose of these questions is to collect descriptive data on the establishment characteristics regarding manager and food worker health policies. Employees working while ill is a critical food safety concern; the Food and Drug Administration (FDA) recommends measures such as restricting the activities of ill workers or excluding ill workers from the establishment. Symptoms of workers should play a key role in a manager's decision-making process when deciding to restrict or exclude workers.

22. When food workers say they are ill, do you typically ask if they are experiencing certain symptoms?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

This question describes whether or not employees are specifically asked about their symptoms (for example, vomiting, diarrhea, fever, etc.). Sometimes employees may volunteer this information, but this question is very specific to the manager asking employees about specific symptoms.

23. Does this establishment have a policy or procedure that requires food workers to tell a manager when they are ill?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → (skip to question 24)

23a. Is this policy written?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

23b. Does this policy require ill workers to tell managers what their symptoms are?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

23c. Does this policy specify certain symptoms that ill workers are required to tell managers about?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → (skip to question 24)

c1. What are those symptoms? (*Check all that apply*)

Select all symptoms the manager specifically states. If the manager gives an answer that is not on the list, select *Other* and clearly describe the symptom.

24. Does this establishment have a policy or procedure to restrict or exclude ill workers from working? By restrict I mean the worker can work, but is not allowed to handle food, and by exclude, I mean the worker does not work at all.

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → (skip to question 25)

24a. Is this policy written?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.

24b. Does this policy specify the specific symptoms that would prompt excluding or restricting ill workers from working?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → (skip to question 25)

24b1. What are those symptoms? (*Check all that apply*)

DO NOT read the answer choices aloud.

Select all the symptoms that the manager specifically states. If the manager gives an answer that is not on the list, select *Other* and clearly describe the symptom.

For this question it does not matter how the manager learns about the symptoms—

whether the manager specifically asks for symptoms or the employee volunteers the information.

Read the following aloud for managers:

READ ALOUD:

The next few questions focus on the food worker and manager sick leave policy. As I read the following questions, please keep in mind that we are asking about managers who have control over the kitchen area or back of the house and food workers that work in the kitchen.

Purpose of Questions 25 and 25a: The lack of manager and worker sick leave is thought to contribute to managers and workers working while ill. The purpose of questions 25 and 25a is to collect descriptive data on manager pay when work is missed due to illness, an establishment characteristic that may be associated with foodborne illness outbreaks.

25. Do any kitchen managers (including you) ever get paid when they miss work because they are ill?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → (skip to question 26)

25a. How many kitchen managers get paid when they miss work because they are ill?

Record the number of kitchen managers at this establishment who receive paid sick leave. If the manager is unsure, select *Unsure*; if the manager refuses to answer the question, select *Refused*.

Purpose of Questions 26 and 26a: These questions mirror the manager questions concerning paid sick leave. It is thought that if both managers and workers receive paid sick leave, they would be less likely to work while ill. The purpose of questions 26 and 26a is to collect descriptive data on the establishment characteristic of sick leave—a characteristic that may be associated with foodborne illness outbreaks.

26. Do any food workers ever get paid when work is missed because they are ill?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → (skip to question 27)

26a. How many food workers get paid when they miss work because they are ill?

Record the number of food workers at this establishment who get paid when they miss work because of illness. If the manager is unsure, select *Unsure*; if the manager refuses to answer the question, select *Refused*.

27. Have any practices or policies changed since you were first notified about a potential problem in your restaurant?

- Select *Yes*, *No*, *Unsure*, or *Refused* based on the manager's response.
- If *No*, *Unsure*, or *Refused*, → End Interview

27a. What were those changes?

The purpose of this question is to determine if any of the policies and/or procedures we are

asking the manager about have been recently modified. For example, we ask about the employee health policy and restriction/exclusion of ill workers. It is possible at the time of the outbreak they did not have an employee health policy but instituted one after they discovered an issue (i.e. outbreak) and before the EA was initiated (or interview was conducted). Another example may include the change of a cleaning policy after an issue occurred. A customer may have vomited in the customer area and, as a result, the establishment instituted a policy to address clean-up of a contamination event. These policies and procedures only relate to the questions asked in manager interview. Please record the manager's response and any other important details that help explain the change.

Read the following aloud for managers:

READ ALOUD:

Thank you very much.

End of Manager Interview

Part IV: Establishment Observation

Purpose of Part IV: This section collects information about the food establishment based on observations of the facility and the practices used during the environmental assessment (EA). This section should be completed as early in the investigation process as possible (preferably within 24-48 hours of the establishment being identified for an EA). Data collection for this section should take place during the establishment's hours of operation if at all possible.

The purpose of these questions is to describe existing circumstances and practices before employees are influenced by the fact that an outbreak investigation is underway. These observations are based on what can be observed at the time of the initial visit to the establishment. Physical facilities and food handling practices are expected to be very similar to those during the time the exposures occurred.

The observation should include information gathered from all visits associated with the EA, such as a visit in response to an illness complaint. If the complaint turns into an outbreak, the information gathered during prior visits is essential to collect for the EA and record in the NEARS instrument.

The answers to questions 3-21 may be a compilation of information gathered by several environmental health specialists involved in the EA. With the exception of question 21, these questions do not relate to conditions that may have been present at the time of the exposure(s), rather they relate to the observed conditions at the time of the EA.

In question 22, please note any physical facility features and/or food handling practices that were significantly different during the time the exposures occurred. You can get this information

- during interviews with managers, food handlers, and others who may know about the circumstances related to the exposure(s);
- through record reviews, and/or
- after developing food flows or other methods used to depict actual circumstances before exposure.

For questions 23 and 24, an environmental health specialist will need to conduct some verification through review and observation. For questions 23, the data collector will have to identify if there is a certified kitchen manager present during the data collection and observe the certification is present and not expired. For question 24, the data collector will have to review the establishment's written employee health policy to verify it contains several components.

REMEMBER: Answer these questions based on what you see, **NOT** on the regulatory requirements for your program. For example, it does not matter if the regulatory requirement for your program is 45°F for cold holding. Take food temperatures and answer the questions according to the temperatures taken.

Individuals conducting the EA must be properly equipped to answer these questions, including having appropriately calibrated thermometers and sanitizer testing equipment. Observations should be based on what is actually observed at the time of the observation, not necessarily on what is reported by the facility manager. The purpose of data gathered through EA observations is to identify the practices that are being used in the restaurant, not to test the manager's knowledge.

Therefore, the evaluator must be prepared with all of the appropriate, properly calibrated equipment needed to take measurements and evaluate the establishment and practices and not depend on information from the managers, workers, or equipment in the facility.

General Instructions for Part IV: Answer these questions based on an EA of the establishment. Base your responses on what you observe at the time of the EA. Although the time required to conduct an assessment might vary depending on the size of the facility and the complexity of the food processes used, expect to spend at least 60 minutes observing the facility and employee practices.

1. How long was the observation (s)?

Track the time you began the observation and the time you complete the observation. Record how many total minutes it took from start to finish. If the observation isn't completed in one visit, add the times for the multiple attempts (to complete observation) together. This is to assess the burden of time needed to complete observation.

2. Date observations were initiated (MM/DD/YYYY).

Indicate the date the observation was initially conducted in the facility.

Dates in Part II (Establishment Description), question 1 and question 2 and Part III (Manager Interview), question 2 may or may not be different from the date observations were made at the facility.

Purpose of Questions 3-4: These questions quantify the number of hand sinks available for use in the establishment and whether they are properly stocked for use. It is thought that multiple, fully equipped hand sinks lead to higher employee use. The purpose of these questions is to collect descriptive data on characteristics of establishments' sinks—characteristics that may be associated with foodborne illness outbreaks.

3. How many hand sinks are in or adjacent to the employee restrooms?

Record the total number of accessible and functioning hand sinks you observe for employee use including hand sinks that are both in the restrooms and adjacent to the restrooms. Only include the adjacent hand sinks if they are separate from the kitchen hand wash sink. If employees use the same restrooms as clients do, record the total number of hand sinks accessible and functioning in all restrooms. Blocked or nonworking hand sinks are not considered accessible and functioning and should not be counted as hand sinks. If *None*, → (skip to question 4)

3a. *If there is at least one hand sink in the employee restrooms: Is warm water (minimum 100°F) available at all employee restroom hand sinks?*

Test the water temperature and select *Yes* or *No*. If *No*, specify the number of sinks without warm water of at least 100°F for any reason (for example, no mixing faucets).

Use a thermometer to find out if the warm water is at least 100°F at all the restroom sinks you counted in question 3. If warm water is not available in some sinks, answer *No* and specify the number of those sinks. Answer *No* for sinks that do not have mixing faucets.

3b. *If there is at least one hand sink in the employee restrooms: Is soap available at (or near) all employee restroom hand sinks?*

- Select *Yes* or *No* for whether there is soap at or near all hand sinks you counted in question 3.
- If *No*, please specify the number of those sinks **without** soap available or nearby.

3c. *If there is at least one hand sink in the employee restrooms: Are paper or cloth drying towels or electric hand dryers available at (or near) all employee restroom hand sinks?*

- Select *Yes* or *No* for whether towels or electric air hand dryers are available at or near all hand sinks you counted in question 3.
- If *No*, please specify the number of those sinks **without** paper or cloth drying towels or electric hand dryers available or nearby.

4. How many hand sinks are in located in the work area?

Record the total number of hand sinks you observe in the work area. Include information on sinks in the work area that meet the jurisdictional definition of a hand sink. (Count all hand sinks regardless if they have soap, sanitizer, warm water, drying towels, etc. that employees could use to wash their hands.) If a hand sink is missing a critical component you will indicate the number of hand sinks in 4a-4c. If *None*, → (skip to question 5)

4a. *If there is at least one hand sink in the work area: Is warm water (minimum 100°F) available at all hand sinks in the work area?*

Test the water temperature and select *Yes* or *No*. If *No*, specify the number of sinks without warm water of at least 100°F for any reason (for example, no mixing faucets).

Use a thermometer to find out if the warm water is at least 100°F at all the restroom sinks you counted in question 4. If warm water is not available at some sinks, select *No* and specify the number of those sinks. Select *No* for sinks that do not have mixing faucets.

4b. *If there is at least one hand sink in the work area: Is soap available at (or near) all hand sinks in the work area?*

- Select *Yes* or *No* for whether there is soap at or near all hand sinks you counted in question 4.
- If *No*, please specify the number of those sinks **without** soap available or nearby.

4c. *If there is at least one hand sink in the work area: Are paper or cloth drying towels or electric hand dryers available at (or near) all available hand sinks in the work area?*

- Select *Yes* or *No* for whether towels or electric hand dryers are available at or near all hand sinks you counted in question 4.
- If *No*, please specify the number of those sinks without paper or cloth drying towels or electric dryers available or nearby.

Purpose of Question 5: The purpose of question 5 is to collect descriptive data on the handwashing practices that you observe during the EAs – practices that may be associated with foodborne illness outbreaks. Base your response on **all** handwashing practices you observe throughout the EA.

5. Are food workers observed washing their hands using water, soap, appropriate drying methods, and for the appropriate amount of time?

- Select *Yes* if the food workers you observed washing hands throughout the EA, washed their hands with soap, used either a towel or electric hand dryer, and washed their hands for the appropriate length of time.
- Select *No* if you observed **any** food worker not wash their hands during the EA as described above. The data collector should spend time to observe the handwashing practices of the food workers.

Purpose of Question 6-7a: The purpose of questions 6, 6a, 7 and 7a is to collect descriptive data on both the establishment characteristics of cold storage units and the temperature of food stored in the cold storage units, a characteristic that may be associated with foodborne illness outbreaks. Based on the U.S Food and Drug Administration (FDA) Food Code, time/temperature control for safety (TCS) foods stored in cold storage units must maintain a temperature of 41°F or lower, which is the NEARS standard. Using this national standard is necessary because some states recommend 45°F in cold storage areas.

6. How many cold storage units are in the establishment?

Indicate the total number of cold storage units you see in operation at the establishment. Cold storage units include walk-ins, reach-ins, self-serve/salad bar, or open top units where food is stored to keep it cold. **This does not include freezers.** If *N/A*, → (skip to question 7)

6a. If there is at least one cold storage unit: Which types of units did you observe? (Check all that apply)

Select all the types of cold storage units you see in the establishment.

7. Are any foods observed in cold holding?

- Select *Yes*, *No*, or *N/A* based on your observations.
- If *No* or *N/A*, → (skip to question 8)

Base the response only on what you see at the time of the EA. This should include food in walk-in, reach-in, open-top, cook line, and other cold holding units. Even if you know the facility uses cold holding at other times of operation, only indicate based on what you observe in conjunction with the EA. However, if pathogens highly associated with holding errors (pathogen proliferation) are suspected in the outbreak, you should make all efforts to observe cold holding processes and ensure proper cold holding temperatures.

7a. If cold holding is observed: Are the temperatures of all foods measured in cold holding at 41°F or below?

Based on your measurements, select *Yes* or *No*. Select *No* for this question if **any** foods in cold holding had a measured temperature above 41°F during your EA.

Cold storage temperature of 41°F or lower is based on the FDA Food Code, which is the standard for NEARS. Using this national standard is necessary because some states recommend a 45°F cold holding temperature. If one or more foods in cold holding are maintained at a temperature above 41°F, select *No* even though it may meet your local recommendations.

Purpose of Question 8: Lack of wearing gloves or using other barrier methods to prevent bare-hand contact may be associated with viral outbreaks. The purpose of this question is to collect descriptive data on the practices you observed related to glove use or use of other barrier methods that prevent bare-hand contact. Base your response on what you see at the time of the EA.

8. Which of the following practices, if any, are observed during this visit? (*Check all that apply*)
Select all the following practices you observed during your visit.

Purpose of Question 9: This question provides information about glove use policy implementation. If there are no gloves in the establishment, it is not possible to implement glove use policies.

Additionally, although you may not see any workers using gloves, they may still be used in the establishment. Base your response of what you see at the time of the EA.

9. Is there a supply of disposable gloves available in the establishment?

- Select *Yes*, *No*, or *N/A* based on your observation.

10. Are there records to indicate that the temperatures of incoming ingredients are being taken and recorded?

- Select *Yes*, *No*, or *N/A* based on your interview and observations.

This includes temperature logs or other temperature control records for incoming food deliveries. Ask if these logs are maintained; if they are, review them and verify they exist and contain temperature data. Complete this question even if the implicated food item does not require temperature control for safety.

11. Are there records to indicate that the temperatures of foods, excluding incoming ingredients, are being taken and recorded?

- Select *Yes*, *No*, or *N/A* based on your interview and observations.

This includes temperature logs or other temperature control records. Ask if these logs are maintained; if they are, review them and verify they exist and contain temperature data. Complete this question even if the implicated food item does not require temperature control for safety.

Purpose of Question 12: This data will be used as an indicator of cross-contamination potential in the establishment and of poor food safety knowledge, food safety culture, and management practices.

12. Is there any evidence of direct cross-contamination of raw animal products with ready-to-eat foods?

- Select *Yes*, *No*, or *N/A* based on your interview and observations.

Direct cross-contamination means that juices from raw animal products come in contact with ready-to-eat foods. This question may or may not be relevant to the food handling practices associated with the outbreak food.

Example: Juice from raw hamburger packages leaking onto a box of cabbage below and soaking

through to the cabbage.

12a. If there is evidence of cross contamination: Describe:

Provide a short, detailed explanation of the evidence observed.

13. Is there any evidence of cooling of hot foods observed in this establishment?

- Select *Yes*, *No*, or *Could Not Observe* based on your observations.
- If *No* or *N/A*, → (skip to question 14)

Base the response only on what you see at the time of the EA. It might not include all types of cooling the establishment uses depending on the processes occurring during the time of the EA. However, if pathogens highly associated with cooling errors are suspected in the outbreak, you should make all efforts to observe this particular cooling processes.

13a. If there is cooling of hot foods: What cooling method(s) are used? (Check all that apply)

Select all options that apply. If the answer is not listed among the choices, describe cooling method in the space provided next to *Other*. Base this response on what you see at the time of the EA. If improper cooling is observed, select the methods used and continue to 13b to select *No*. If proper cooling is observed or there is evidence of it, select the methods that are being used.

During the EA look for any foods that are actively cooling to determine the establishment's cooling methods. If there are no foods observed actively cooling during your visit, look for foods in the refrigerator that were previously cooked and cooled prior to your visit. Take temperatures of the cooked food items and establish when they were prepared. To help determine the cooling methods used by that food establishment, ask the Person in Charge how they cooled those food items and have them show you any equipment used (blast chiller, shallow pans, ice wands, etc.). Examples of observations that may help you determine the cooling methods used include, but are not limited to, a speed rack with shallow pans stacked in it and ice wands observed in the freezer and/or in pans of food. If pathogens highly associated with cooling errors are suspected in the outbreak, you should make all efforts to observe this particular cooling process.

13b. If there is cooling of hot foods: Were the cooling methods properly implemented?

- Select *Yes*, *No*, or *Undetermined* based on your observations and the evidence observed.

Examples of some evidence that you may observe to help you determine improper cooling methods were used include, but are not limited to, large pans of prepared foods that were never portioned into smaller, shallow pans, condensation observed on large pans or pots of prepared foods in refrigerators and large, whole cooked meats that were never sliced or portioned into smaller pieces and no blast chiller present. If pathogens highly associated with cooling errors are suspected in the outbreak, you should make all efforts to observe this particular cooling process.

14. Are any foods observed in hot holding?

- Select *Yes*, *No*, or *N/A* based on your observations.
- If *No* or *N/A*, → (skip to question 16)

Base the response only on what you see at the time of the EA. This should include TCS food in steamtables, hotboxes, or other hot holding units. Even if you know the facility uses hot holding at other times of operation, only indicate based on what you observe in conjunction with the EA. However, if pathogens highly associated with holding errors (pathogen proliferation) are suspected in the outbreak, you should make all efforts to observe hot holding processes and ensure proper hot holding temperatures.

14a. If there are foods in hot holding: Are the temperatures of all foods measured in hot holding at 135°F or above?

Based on your measurements, select *Yes* or *No*. Select *No* for this question if **any** foods in hot holding had a measured temperature below 135°F during your EA.

Purpose of Questions 15 and 15a: The term “cooked” is used in the broadest sense. It includes foods that are cooked for service, such as pasta noodles, that become TCS after cooking, as well as foods such as raw animal products that require a specific temperature for pathogen destruction.

In both of these examples, the correct answer to this question would be *Yes* if food was cooked to the appropriate temperatures for these specific items. If one cooked food is not cooked to the recommended temperature, *No* is the correct response. For example, if a raw ground hamburger was not cooked to 155°F, answer *No*.

15. Are any foods observed during cooking?

- Select *Yes*, *No* or *N/A* depending on whether you observed any foods during cooking.
- If *No* or *N/A*, → (skip to question 16)

15a. If there are foods cooking: Are the temperatures of all foods measured during cooking at or above the recommended temperatures?

Based on your measurements, select *Yes* or *No*. Select *No* for this question if **any** foods being cooked had a measured temperature other than that recommended by the FDA for cooking/heating/reheating. Use the FDA cooking/heating/reheating temperatures as your guide.

16. Are there any thermometers observed in food preparation areas to measure internal food temperatures?

- Select *Yes*, *No* or *N/A* based on your observations. This includes any thermometer that will be used to take an internal temperature of food, not thermometers that will be used to take an ambient temperature.
- If *No* or *N/A*, → (skip to question 17)

16a. If there are thermometers observed: Are any thermometers observed being used?

- Select *Yes* or *No* based on your observations.

Purpose of Questions 17-17b: These questions assess if sanitizer items are available, but not

necessarily in use, at the time of the observation. Base your responses on what you see throughout the EA.

17. Are any of these items observed for cleaning and sanitizing food contact surfaces and in-place equipment? (Check all that apply)

Select all the items you identify that the establishment uses for cleaning and sanitizing throughout the EA.

17a. If wiping cloths are in use: Are all wet wiping cloths stored in sanitizer solution between uses?

- Select *Yes* or *No* based on your observations.
- Select *Not in use* if the establishment does not have sanitizer buckets or sanitizer bottles in use.

17b. If sanitizer buckets or bottles are in use: Pick one sanitizer bucket (or bottle) and test sanitizer concentration. Is it in the proper range?

Choose one sanitizer bucket or sanitizer bottle and check the concentration of the sanitizer solution.

- Select *Yes* if the concentration of the solution is within the appropriate range for that chemical.
- Select *No* if the concentration is not within the appropriate range for that chemical.
- Select *Not in use* if the establishment does not have sanitizer buckets or sanitizer bottles in use.

18. Which of the following methods does the establishment use to clean dishes, utensils, or other food equipment that is not cleaned in place? (Check all that apply)

Identify how the restaurant cleans and sanitizes its dishes. If a machine is used, select *Mechanical Washing Machine* and proceed to 18a-18b. If the mechanical washing machine is not in use at the time of your visit, but is the primary method of washing, rinsing, and sanitizing dishes and utensils, ask the Person in Charge to turn on the dishwasher so you can verify that it works properly. If the machine has been off and not in use, allow time for the dishwasher to get up to the proper temperature and run for machine for a few cycles before verification of the temperatures. Prior to verification of the sanitizer concentration, allow the sanitizing rinse to flow through lines in order to obtain an accurate measurement. If the mechanical washing machine is in use during your visit and has already been run several times, the temperature and/or concentration of the sanitizer solution should be accurate on the first reading but allow a few attempts before recording your final observation. If there is no one on site that is familiar with how to turn on the dish machine during your visit, select *Mechanical Washing not occurring* for 18a-b.

If dishes are washed by hand, select *Manual washing* and proceed to 18c-d. If the three-compartment sink is in use, verify that dishes are being washed properly. If the three-compartment sink is not set up during your visit, select *Manual washing not occurring* for 18c-d. If the restaurant uses another method, select *Other* and provide a brief description. If the restaurant uses a combination of the above, please select all options (and their subsequent skip patterns) that apply.

18a. If there is a mechanical washer: Does the wash cycle reach the temperatures recommended for that washing machine?

- Select *Yes* or *No*. Refer to the machine's data plate for recommended temperatures and compare that to the observed temperature reached during the wash cycle.
- If there is no one on site that is familiar with how to turn on the dish machine during your visit, select *Mechanical Washing not occurring*.

18b. If there is a mechanical washer: How is sanitization achieved? (Check all that apply)

- If the machine uses heat to sanitize, select *Heat* and continue to 18b1.
- If the machine uses chemical to sanitize, select *Chemical* and continue to 18b2.
- If there is no one on site that is familiar with how to turn on the dish machine during your visit, select *Mechanical Washing not occurring* for 18b1 or 18b2.

18b1. If heat is used to sanitize: Does the sanitizing cycle reach the temperatures recommended for sanitizing?

- Select *Yes*, *No*, or *Mechanical washing not occurring*.

To verify, either 1) Check the external thermometer of the final rinse cycle while it is in use and compare to the data plate, 2) Obtain the final rinse temperature of the plate surface via a temperature sticker or running a maximum-registering thermometer through the machine with the dishes.

If the mechanical ware washer uses a chemical to sanitize and it still meets the plate temperature to sanitize select *Yes*, otherwise select *No* or *Mechanical washing not occurring*. If this is not working and machine is in disrepair, select *Out of order*.

18b2. If chemical used to sanitize: Does the chemical sanitizing cycle have the required levels of chemical sanitizer recommended for the machine?

- Select *Yes*, *No*, or *Mechanical washing not occurring*.

Use the appropriate sanitizer test strips and run it across the surfaces of dishes immediately after the machine has finished its cycle. Compare that result to the required concentration for use in food service settings listed on the chemical label. If this is not working and machine is in disrepair, select *Out of order*.

18c. If there is manual washing: What type of sink is used for manual washing? (Check all that apply)

- Select *3-compartment*, *2-compartment*, or *Other* and provide a brief description.

If manual washing is not occurring at the time of the EA, look for which sink has washing supplies (dish soap, scrub brushes, etc.). If it is still unclear where dishes are washed, ask the Person in Charge.

18d. If there is manual washing: Are dishes, utensils, etc. washed, rinsed, sanitized (either with heat or chemical) properly? (Check all that apply)

- Select *Yes*, *No*, or *Manual washing not occurring*.

Select *Yes* only if items are both washed, rinsed, **and** properly sanitized. This includes if steps were in proper order and that each step was done correctly. This assesses if dishware was washed, rinsed, and then sanitized in either chemical that is at the proper concentration or at the proper temperature for sanitization. Use your test strips or thermometer, depending on the operation, to ensure proper implementation of sanitization. The appropriate contact time must be allowed for proper sanitization. All of these components must be met.

Select *No* if the above conditions are not met and indicate the issues observed. If manual washing not taking place, select *Manual washing not occurring*.

19. Are any signs and instructions posted in the establishment?

- Select *Yes* if you see any type of food safety related instructions or signs in the establishment related to policies and practices.
- Select *No* if you do not see any instructions or signs. → (skip to question 20)

These instructions and signs can be written words only, pictures only, or a combination of the two. Consider any instructions or signs posted in the establishment describing standard operating procedures or policies in response to this question.

Example: Handwashing signs posted at hand sinks to demonstrate proper handwashing or signs in the restrooms instructing workers to wash their hands after using the restroom are both related to policies and practices.

19a. If yes: Do any use pictures or symbols to communicate a message?

- Select *Yes* if you see pictures or symbols meant to communicate a message on any of the signs or instructions posted.
- Select *No* if you don't see pictures or symbols.

Example: At the hand sink you see a poster that shows pictures of how to wash your hands.

19b. If yes: What languages did you observe on signs or instructions posted for food workers? (Check all that apply)

Select all languages you see on posted signs or instructions. This question refers to all signs or instructions. A poster might have instructions in several languages or you might notice several posters in different languages.

Example: You notice a sign with instructions in English and Spanish for thawing ground beef; select *Spanish* and *English*.

Purpose of Question 20: The purpose of this question is to identify if the establishment is prepared to properly respond to vomit and diarrheal events.

20. Did you observe any of these items for responding to vomit and/or diarrheal incidents? (Check all that apply)

The items listed here may or may not be out in the open, therefore it is recommended to ask the Person

in Charge when applicable. Select each item that is observed.

20a. *If any of these are observed: Are any of these things located together (for example: in a kit)?*

If two or more of the items in question 20 are stored together, please select *Yes*. When applicable, ask the Person in Charge if they have a clean-up kit for vomiting or diarrheal incidents as it may not be stored in the kitchen.

21. Are there any differences to the physical facility, food handling practices you observed on your initial visit, or other circumstances that were different at the time of exposure?

- Select *Yes* or *No* based on your EA.

21a. *If there are differences: Describe.*

Please provide a brief description of any changes.

Examples may include, but are not limited to the below:

- the establishment operated with no hot water.
- the walk-in cooler units failed.
- the kitchen manager was on vacation and normal policies or procedures were not followed in their absence.
- the establishment was out of single use gloves.
- a large number of food workers did not show up for work.

22. Record any additional comments.

This section allows a brief description of specific circumstances during or right before the time of the exposures that are believed to have contributed to the outbreak.

23. Is a certified kitchen manager present at the time of data collection?

Determine if a certified kitchen manager is present during your visit by observing posted certificates or by asking the Person in Charge. If a certified kitchen manager is present, review the certificate to determine if it is current or expired, and whether it is from an American National Standards Institute (ANSI)-accredited program (i.e. National Restaurant Association's ServSafe, National Registry of Food Safety Professionals, Prometric, 360 Training, or AboveTraining/StateFoodSafety.com) or is another type of certification. Upon your review, check off all of the answer choices that apply. For example, if the establishment has a certified kitchen manager that is from an ANSI-accredited program, but the certificate has expired you would select *Yes, ANSI certification* and *Certification is not current*. If the certificate is unavailable for review, only select the answer choice *Yes, but certificate is not available*. If a certified kitchen manager is not present at the time of data collection, determine if the food establishment has at least one certified kitchen manager employed at that establishment. If a certified kitchen manager is employed at the establishment, select *No, but has a certified kitchen manager on staff*. If there is no certified kitchen manager during your visit and they do not have a certified kitchen manager employed at that establishment, select *No*. If the establishment is unsure if they have a certified kitchen manager, select *Unsure*.

24. Does the establishment have a written employee health policy or procedure? (Check all that apply)

Ask to see the written health policy and review it for each component. Check all components that apply. Select *Policy not in use* if the establishment has a written employee health policy, due to legal requirements, however it is evident it's not used in practice.

Part V: Confirmed/Suspected Food

Purpose of Part V: A systematic review of the food preparation process of the suspected/confirmed food is necessary to identify contributing factors to the outbreak and to describe the specific foods or food items involved. This section captures specific information on the foods suspected and/or confirmed in the outbreak.

The food flow is often the cornerstone of the environmental assessment (EA) during a foodborne illness outbreak. It is used to describe the flow of the food through the establishment from receiving to service. You can use Form G (page 147) in the International Association for Food Protection (IAFP) *Procedures to Investigate a Foodborne Illness*, 6th edition, to help organize the process and identify critical points in the process where contamination, proliferation/amplification, or survival possibly occurred. A complete EA includes a food flow developed for the foods implicated in the outbreak.

This section should only be completed if a specific food item (multi-ingredient food) or specific food ingredient has been implicated (either confirmed or suspected) in the outbreak (Part 1 [General Characterization], question 10). If no specific food item or specific food ingredient is implicated, → (skip to Part VI [Positive Samples]. Refer to Part I (General Characterization), question 10 for definitions of suspected and confirmed food items).

Answer questions Part Va, questions 1-5, for each suspected/confirmed food; answer questions Part Vb, questions 1-4 for each specific ingredient in the confirmed or suspected food(s).

- In Example 1, you would answer Part Va questions 1-5 for the hamburger sandwich as a whole, then answer questions Part Vb 1-4 for EACH single specific ingredient. If the sandwich included a bun, ground beef, tomato, and lettuce, you would answer questions Part Vb 1-4 four times—once per ingredient—on four different forms.
- In Example 2, you would answer questions ONLY for the confirmed food (lettuce).

If a specific food ingredient or multi-ingredient food is not suspected or confirmed, select *No* in Part 1 (General Characterization), question 10. → (skip to Part VI [Positive Samples])

General Instructions for Part V: In an outbreak investigation a number of food flows may be developed before a food or food item is suspected or confirmed. The following questions are specific to the food item or food ingredient that was ultimately suspected or was confirmed to be the food in the outbreak.

Part Va- Suspected/Confirmed Foods: Complete this section for **EACH** suspected/confirmed food.

1. What is the name of the suspected or confirmed ingredient or food (for example, lettuce or garden salad)?

Provide the name of the confirmed/implicated food item. Note: Name should match Part I (General Characterization), question 10.

Examples:

- Specific ingredient: lettuce, tomato, ground beef, basil, flour
- Multi-food ingredient: hamburger sandwich, garden salad, tortilla soup, salsa, meatballs,

chili

2. Is this food a single specific ingredient (for example, ground beef or lettuce) or multi-ingredient (for example, hamburger sandwich, garden salad)?

- Select *Single Specific Ingredient Food* if the confirmed or suspected item is one Single-Ingredient.
- Select *Multi-ingredient Food* if the suspected or confirmed food included two or more specific Single-Ingredients. In a multi-ingredient food, no one item can be implicated, but the food as a whole has been implicated.

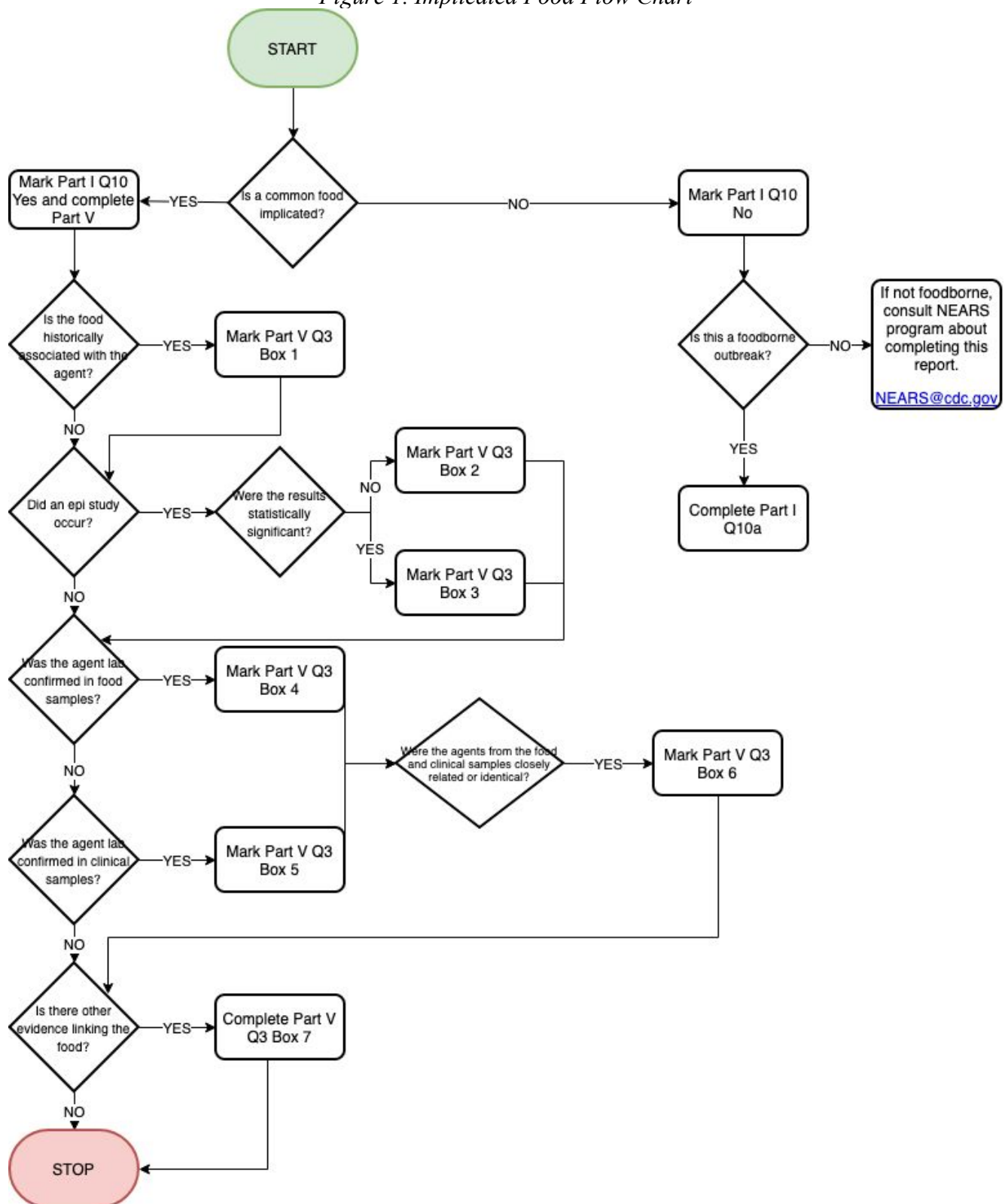
Examples:

- Single specific ingredient food: lettuce, tomato, ground beef, beef, flour, black pepper
- Multi-ingredient food:
 - Hamburger sandwich (bun, ground beef, lettuce, tomato, onion)
 - Garden salad (lettuce, tomato, onion, cucumber, oil, vinegar, and croutons)
 - Meat chili (ground beef, ground turkey, tomato, cayenne pepper, cumin, onion, chili pepper, cheese)
 - Meatballs (ground pork, ground beef, ground turkey, onion, bread crumbs, parsley, black pepper, salt)

3. Select all of the reason(s) that describe how this single specific ingredient or multi-ingredient food was implicated in the outbreak. (*Check all that apply*)

The intent of this question is to determine what the strength of evidence was used to implicate food in the outbreak. Use the flow chart (Figure 1) to determine the reason(s) an ingredient or food was implicated.

Figure 1. Implicated Food Flow Chart



The following guidance is only for individuals who also enter this outbreak into NORS.

When reporting this outbreak into the National Outbreak Reporting System (NORS), indicate what evidence was used to implicate food. The intent of this question is to determine what types of evidence were used and to categorize the food as either a confirmed or suspected source. The following types of evidence are used to implicate foods in NORS:

- **Epidemiologic** - A food exposure occurs more often in case-patients than in controls, or more often in case-patients than expected in the general population. Multiple unrelated case-patients report a common exposure venue, such as eating at the same restaurant, shopping at the same grocery store, or attending the same event before becoming ill.
- **Laboratory** - The pathogen or pathogen subtype causing illness is found in a food item, restaurant, production facility, or farm suspected to be the source of the outbreak. The pathogen, or pathogen subtype, causing human illness is isolated from a food worker to which case-patients were exposed through prepared food.
- **Traceback and/or environmental investigation** - A common point of contamination is identified through reviewing records collected from restaurants, stores, or other venues where sick people ate, shopped, or visited, or through an environmental investigation or assessment conducted at a restaurant, production facility, or farm.
- **Other data (specify in General Remarks)** - Select other data if there is evidence not covered by the previous three options. Provide further details in the “General Remarks” section. Do not select this option if the vehicle is confirmed.

In NORS, food vehicles can be categorized as confirmed or suspected:

- **Confirmed vehicle** - Evidence implicated a source of infection. For point-source clusters linked to a meal or a single even, at least one type of evidence is needed. When exposures occur in multiple venues or across multiple counties or states, at least two types of evidence (not to include “Other data”) are needed to ensure that the case-patients were exposed to a common vehicle. For guidance on multistate outbreaks see [Appendix B](#) of the [NORS Guidance](#).
- **Suspected vehicle** - At least one type of evidence provides considerable but not conclusive proof that a food is the source of infection.

4. Which of the following best describes the food preparation process used for this specific ingredient or multi-ingredient food before consumption?

Select the food preparation process used for this specific ingredient or multi-ingredient food. Base your response on the food flow conducted.

Review the following food processes and select the one that best describes the process used for this specific ingredient or multi-ingredient food (based on the most complex ingredient):

- **Prep Serve** – Did NOT involve a kill step and may be followed by hot holding but is prepared for same-day service.
- **Cook Serve** – Involved a kill step and may be followed by hot holding but is prepared for same-day service.
- **Complex 1** – Involved a kill step, followed by holding beyond same-day service.
- **Complex 2** – Involved a kill step, followed by holding and cooling.
- **Complex 3** – Involved a kill step, followed by holding, cooling, and reheating.
- **Complex 4** – Involved a kill step, followed by holding, cooling, freezing, and reheating.

Examples:

- In Example 1, the hamburger sandwich is the implicated food in the outbreak and no specific ingredient was identified as the food. The correct response to this question using Example 1 is based on the most complex process used to prepare the food item. For a hamburger sandwich that would be *Cook Serve* because the ground beef was cooked for same-day service. All the specific ingredients of the hamburger sandwich (for example, ground meat, lettuce, tomatoes) would also be entered in the ingredient description section.
- In Example 2, the implicated hamburger sandwich may be best described as a *Cook Serve* food item, but the lettuce, which was implicated in the outbreak, is a *Prep Serve* ingredient. The correct response to this question using Example 2 would be *Prep Serve* and only the lettuce would be entered into the ingredient description.

5. 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?

- Select *Yes* or *No* based on the investigation.
- If *No*, → (skip to Question 7)

5a. If yes, how would they be best characterized? (Check all that apply)

Select the best description(s) of differences. If an event does not match those listed, select *Other* and describe circumstances as clearly as possible.

Ingredient Description

Part Vb- Suspected/Confirmed food, ingredients

Answer questions 1-4 separately for each ingredient identified as a suspected/confirmed food in this outbreak.

- If a single specific ingredient, such as lettuce, is identified as the food, fill this form out once. The response to Part Vb, question 1 will be the same as the answer to Part Va, question 1.
- If a multi-ingredient food, such as garden salad, is identified as the food, fill out a separate sheet for EACH ingredient of the multi-ingredient food. The response to question Part Vb 1 will be the specific name of the ingredient for which questions 2-4 will correspond.

Example: Meatballs were identified as the implicated food item. During the EA, the evaluator would work with the manager and food workers to identify whether the meatballs are made in house or purchased premade. The evaluator would also gather information on the ingredients used to make the meatballs and how they were prepared.

In this example, the meatballs are prepared in house and the manager and food workers identified the following 10 ingredients: beef ground fresh on premises, pork ground fresh on premises, milk, shelled eggs, bread crumbs, parmesan cheese, garlic, oregano, parsley, black pepper, salt.

So in questions Part Va, questions 1-5, the evaluator would describe the meatball as a food item and then fill out questions 1-4 for EACH of the 10 specific ingredients that are used to make the meatball. The answer to Part Va, question 1 would be meatball and the response to Part Vb, question 1 would be

the specific name of the ingredient—that is, ground beef.

1. Name of ingredient.

- For single specific ingredients, enter the same answer as the answer to question 1.
- For multi-ingredient food, list the name of the single specific ingredient that is described in the answers to Part Vb, questions 2-4.

Example: A garden salad is the implicated food item. The answer to Part Va, question 1 would be garden salad and the answers recorded for Part Vb, question 1 would be the names of the specific ingredients that make up the salad—e.g., romaine lettuce, tomato, onion, cucumber, oil, vinegar, salt, and pepper.

2. If any information present (product manifests, records, tags, etc.) that shows this ingredient is an imported food item or from an unapproved source or recall, describe:

Describe the information used to indicate this is an imported food item (receipt information such as company, location of origin, lot number, tag numbers, etc.). For example, indicate in the description if it was based on a manager report. Also indicate any information that they can provide and that documentation was not available at the time of the EA.

Example: An imported anchovy had been used in a daily special that is implicated in the outbreak. All the anchovies had been used in the special and no packaging items or receipts for the item remain. It would be appropriate to record that as “No product labels or receipts were present at the time of the environmental assessment”. However, according to the manager, they used XX brand of anchovies purchased from YY wholesaler on approximately XX/XX/XXXX and the product came from ZZ and the label had a picture of WW on it.

3. Did any of the following intend for the food to be consumed raw or undercooked? (Check all that apply)

Select the best reason(s) that a food was intended to be consumed raw or undercooked. If the reason is unknown or the food was not intended to be consumed raw or undercooked, select *Unknown* or *N/A*, respectively.

Example: A hamburger sandwich was implicated in the outbreak and during the EA; the evaluator would work with the manager and food workers to determine if the ground beef patty was requested to be undercooked by the consumer and/or establishment for consumption. The observation of a consumer advisory for this item of a menu or placard may indicate this food was intended to be consumed undercooked. This may involve checking receipts/tickets to verify the customer ordered the hamburger undercooked, but the establishment may not keep these records. If raw oyster was implicated, this was intended to be consumed raw by all (processor, establishment, and consumer).

4. If the ingredient is:

a. Poultry, Select the type.

Select only one type.

b. Seafood, Select the type.

Select only one type.

c. Beef, pork, lamb, other meat, Select the type.

Select only one type.

d. Poultry, seafood, beef, pork, lamb, other meat, Select the best description of the product upon arrival at the food service establishment.

Select only one description.

- *Raw, Nonfrozen* – refers to animal or seafood proteins that are received in the establishment raw and unfrozen (e.g., beef, poultry, pork, etc.).
- *Raw, Frozen* – refers to animal or seafood proteins that are received in the establishment raw and frozen (e.g., beef, poultry, pork, etc.).
- *Raw, Intended for Raw Service* – product may be frozen or nonfrozen but is intended for raw service (e.g., oysters or seafood used for sushi).
- *Commercially Processed Precooked: May Require Heating for Palatability* – refers to commercially processed animal or seafood protein that has been precooked and does not require further cooking (e.g., various types of deli meats such as hot dogs, deli sliced ham, canned spam, etc.). Also refers to commercially processed animal protein that may require heating for palatability (e.g., fully cooked frozen fish sticks that are heated for service).
- *Commercially Processed: Further Cooking Required* – refers to commercially processed animal or seafood proteins that require further cooking (e.g., chicken nuggets that require full cooking, preformed hamburger patties, etc.).
- *Dried/Smoked* – refers to commercially processed animal or seafood proteins that have been dried or smoked as part of the processing process as a means of preservation.
- *Other* – If the specific ingredient does not match one of these categories, check *Other* and describe the condition of the ingredient when it entered the food service establishment. Before you select *Other*, please review the available categories carefully and make sure the condition of the ingredient does not match one of the existing categories.

e. Dairy, Select the best description of the product upon arrival at the food service establishment.

Select only one of the five descriptions

- *Pasteurized Fluid Milk* (includes all types of pasteurization)
- *Unpasteurized Fluid Milk*
- *Pasteurized Dairy Product* (frozen or nonfrozen, liquid or dried) (includes any pasteurized dairy product that is not fluid milk or cheese). Describe the product in the space provided.
- *Unpasteurized Dairy Product* (frozen or nonfrozen, liquid or dried) (includes any unpasteurized dairy product that is not fluid milk or cheese). Describe the product in the space provided.
- *Cheese*. Describe the product in the space provided.

f. Eggs, select the best description of the product upon arrival at the food service establishment.

Select only one of the three descriptions. Describe the product in the space provided.

- *Pasteurized In-shell Eggs*
- *Pasteurized Egg Product* (frozen or nonfrozen, liquid or dried)
- *Unpasteurized Egg Product* (frozen or nonfrozen, liquid or dried)

g. If ingredient is a plant or plant product, Select the type.

Select only one of the six descriptions. Describe the product in the space provided.

- *Produce*
- *Fruit*
- *Fungi*
- *Nuts/Seeds*
- *Grains/Cereals*
- *Grain/Cereal Products*

The *Produce* categorization is broad; question 4h provides more specificity.

Although tomatoes are technically a fruit, classify tomatoes as *Produce* for the purposes of this data collection.

h. If ingredient is produce, Select the type.

Select only one of the four descriptions. Describe the product in the space provided:

- *Greens* – Lettuces and other leaf type produce that is eaten. Examples include iceberg lettuce, spring mix, and spinach.
- *Sprouts* – Shoots of plants usually from recently germinated seeds and not fully grown. Sprouts include bean sprouts, alfalfa sprouts, and broccoli sprouts.
- *Root Vegetable* – Vegetables that grow below ground. Root vegetables include potatoes, carrots, onions, and turnips.
- *Vine or Above ground Vegetable* – Vegetables that grow above ground or on a vine. These vegetables include beans, peppers, eggplant, tomatoes, and squash.

If you do not know if a vegetable is a root vegetable or a vine or above ground vegetable, consult your local extension office.

i. If ingredient is a plant or plant product, Select the best description of the plant product upon arrival of the product to the food service establishment.

Select only one of the six descriptions:

- *Raw, Whole, Nonfrozen, Fresh* (examples include heads of lettuce, green beans, unshelled peas)
- *Commercially Processed – Fresh Product* (examples include bagged lettuces, fresh carrots, fresh chopped peppers, shelled pecans, walnuts)
- *Raw, Frozen* (examples include frozen corn, frozen peas, frozen strawberries)
- *Commercially processed – canned, other* (examples include canned beans, canned corn)
- *Dried* (examples include dried peas)

- *Other – Describe*

j. If ingredient is not described in the previous categories, Describe the ingredient.

Provide a description of the ingredient in the text box.

Part VI: Positive Samples

Purpose of Part VI: Complete this section for EACH positive sample. This section provides information on any environmental sampling. For the purpose of NEARS, reported sampling includes **only environmental sampling** (either food or environmental samples); it does not include human samples, such as vomit or feces samples. It should include all samples taken as a part of the environmental assessment (EA), including presence/absence, detect/non-detect, or specific value (e.g., X ppm or X cfu/g) samples.

General Instructions for Part VI: Use the section titled Collect Samples of Suspect Food in the International Association for Food Protection (IAFP) *Procedures to Investigate a Foodborne Outbreak Investigation, Sixth Edition* (pages 41-44) as a general guide for collecting food samples. Additionally, you can use the Food Sample Collection Report (Form F on page 146 of the IAFP procedures) as guidance for food sample collection.

Each person collecting the samples should follow the specific instructions of the analyzing laboratory for the food and/or environmental samples collected.

Provide sample number and the date the sample was collected at top of Part VI for every positive sample.

Purpose of Questions 1, 2 and 3: These questions will provide information on each specific environmental or food sample that was taken and processed during the EA to help characterize each sample. This will help us understand what agents were found in the samples and where they were taken from in the establishment and provide insight about each individual sample. Provide information only on positive samples.

Please answer questions 1-3 separately for each positive sample taken in this outbreak. If only one sample was taken, answer questions 1-3 once. If multiple samples were taken, then answer questions 1-3 for EACH sample.

1. Describe the agent(s) found in the sample.

a. **Agent. (Check all that apply)**

Select the response(s) that most closely corresponds to the agent(s) found in the sample. If the appropriate answer is not available, select the most appropriate choice (*Toxic Agent, Chemical Hazard, Physical Hazard, or Other*) and describe the specific agent identified.

b. **Serotype, if identified.**

If a serotype was identified from the sample, then describe the serotype.

c. **Match to clinical sample.**

If there was a match to clinical sample, select *Yes*.

2. Where was the sample taken from?

Select the response that most closely corresponds to where the environmental sample was taken in the establishment. If none of the answer choices are appropriate, select *Other* and concisely describe the location where this sample was taken from.

If sample was taken from a food ingredient then provide the name of the specific food ingredient (the name given below should match the specific food name given in Part Va) or multi-ingredient food (the name given below should match the multi- ingredient food name given in Part Vb).

3. Provide any other information about the specific sample.

Provide any additional information that would help characterize the specific sample. Include presence/absence, detect/non-detect, and results with a value (pH, X ppm, X cfu/g). This could also include any information collected on site from the packaging, labeling, or invoices that would help with traceback/traceforward (brand name, name of manufacturer, address, production date, container size, etc.), information about the point of operation where the sample was taken, how the sample was prepared and shipped, and more.

Part VII: Contributing Factors

Purpose of Part VII: The purpose of Part VII is to capture the likely contributing factors identified for an outbreak, given the epidemiological, the environmental health, and the laboratory evidence collected during the foodborne illness outbreak investigation. Contributing factors (CFs) are defined as the practices that most likely contributed to a foodborne illness outbreak. The CFs help determine what the root cause was for an outbreak in regard to the contamination, proliferation, or survival of microorganisms or toxins in the implicated food source. Careful consideration must be given to the context of the foodborne illness outbreak and the information gathered during the environmental assessment (EA) to determine the most likely contributing factors.

Although some contributing factors may correlate to code violations, contributing factors are **NOT** code violations. Contributing factors are the most likely factors to contribute to the contamination, proliferation and survival of the etiologic agents or suspected agents associated with the outbreak investigation. Contributing factors, such as inadequate cooking temperatures, are recognized by public health authorities and control measures have been identified for them.

The EA must be conducted so that the root cause(s) of the outbreak can be better understood. The causes can be related to both failure to implement recognized control measures and identification of previously unrecognized control measures.

EAs include but are not limited to

- A visit to the location where implicated foods are grown, harvested, processed, prepared and/or served;
- A review and observation of the physical facilities, the equipment and the food handling processes used;
- Interviews with those involved in the growing, harvest, processing, distribution, handling and/or preparation of the implicated foods;
- A review or collection of the menus or records related to growth, harvest, processing, distribution, and/or handling of foods at point of final service in food-service establishments such as restaurants, delis, quick service restaurants, or institutional food service facilities including schools, nursing homes, and hospitals;
- Development of a food flow diagram for implicated foods that includes notes on preparation policies and practices; points of possible contamination, proliferation, and/or survival; and individuals involved, and/or;
- Reenactment of the preparation of foods involved in the outbreak.

The information gathered in Part VII will be used to help us understand how the outbreak likely evolved.

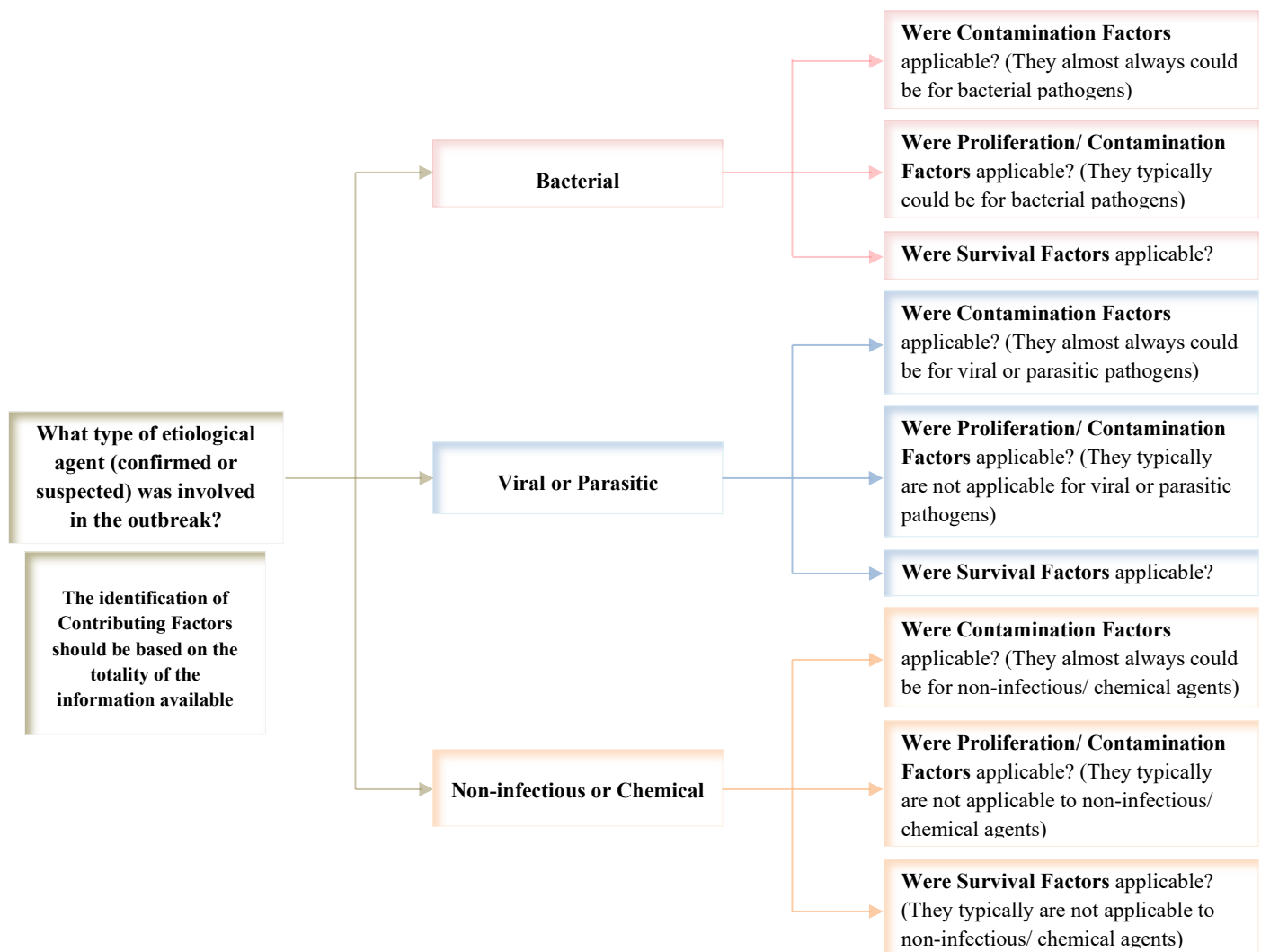


Figure 1. Flow Chart to Determine Contributing Factor

Although you may find risk factors during the EA, ensure the contributing factor is related to the pathogen of interest. Below is an example to consider in a norovirus outbreak. Refer to Figure 1 during review of this example.

- Proliferation factors are not appropriate citations in a norovirus outbreak because norovirus does not proliferate outside the host.
- Survival factors may be appropriate citations in a norovirus outbreak in instances where high temperatures were used in the food handling process. High temperatures will inactivate norovirus. If failure to implement high temperatures played a role in a norovirus outbreak, citation of survival factor(s) may be appropriate.
- Contamination factors are appropriate citations in a norovirus outbreak.

Note: Sometimes there is confusion about whether an outbreak is foodborne or waterborne. In general,

waterborne outbreaks include contamination occurring in the source water or in the treatment or distribution of water to the end consumer. For example,

- If water entering a drink mix/soda machine is contaminated or if there is a problem with the internal plumbing of the machine resulting in contamination (e.g., cross-connections, backflow of carbonated water resulting in copper leaching)—it's waterborne.
- If ice is made with contaminated water—it's waterborne.
- If ice is already made and then it becomes contaminated through handling because it was stored in a toxic or contaminated container—it's foodborne.

Contact CDC staff if you have any questions about how to determine whether an outbreak is a foodborne or waterborne outbreak.

General Instructions for Part VII: Contributing factors are identified as a result of a foodborne illness outbreak EA. They generally reflect factors specific for the location where the exposures occurred. Contributing factor identification should not be based on an EA alone—it should be based on all the available information gathered during the investigation, including epidemiological and laboratory information.

Contributing factors can be reported in all outbreaks, even those in which an agent or food has not been identified. For example, while an agent may not be known, symptoms of the ill can indicate whether the agent is likely bacterial, viral, or a toxin:

- If bacterial, a focus on time temperature abuse would be appropriate.
- If viral, a review of employee health or hygiene before the exposure of those who are ill would be appropriate.
- If a toxin, a review of how toxic agents are handled in the establishment or a focus on toxin-producing food processes would be appropriate.

A factor should be reported only if the investigator has strong evidence that it actually occurred in this outbreak. Contributing factors should not be reported based on assumptions.

When a specific location is clearly identified in an outbreak event, an EA can be initiated using the available outbreak information.

For additional guidance, two sections in the International Association for Food Protection (IAFP) *Procedures to Investigate Foodborne Illness* sixth edition can be used to help determine contributing factors to the outbreak:

- Table B, Illnesses Acquired by Ingestion of Contaminated Foods: A Condensed Classification by Symptoms, Incubation Periods, and Types of Agents (pages 109-126) and
- Keys A through H (pages 79-98).

Answers to questions in Part VII should be based on all available information collected regarding the outbreak and EA as well as the professional judgment of the evaluator, and NOT always just on absolute proven fact. Communication and collaboration among all the outbreak team including communicable disease control (epidemiological) authorities and clinical and food laboratory authorities are critical in answering these questions. In addition to information provided by the communicable disease control and laboratory authorities, consider the following

when determining an answer:

- Information gained from the outbreak EA,
- Circumstances observed in the establishment,
- Interviews with those involved in preparing the suspect food item, and
- Known scientific data concerning the illness and pathogens.

Only check a contributing factor if the investigation team has evidence that it occurred in this outbreak—just because a factor has been cited in similar outbreaks does not mean it was involved in this outbreak. Assess all information about the outbreak when determining the contributing factors. Along with others on your investigation team, carefully consider each contributing factor and the evidence supporting it. Doing so will help ensure that these inferences are valid.

Primary Contributing Factor

Multiple contributing factors can be cited in any outbreak. An investigator should use their professional experience to assess which of the contributing factors should be considered the primary contributing factor for the outbreak. Several factors can contribute to an outbreak because many outbreaks evolve via a string of events that result in one factor affecting another, then another. When determining the primary factor, consider all the circumstances and events associated with the outbreak. Using this information, select the contributing factor that seems the most likely to be the first event that had the greatest impact on the evolution of the outbreak.

Examples:

- The outbreak investigation reveals that hamburger patties were undercooked at a church supper that were served to all the sick individuals [S1: *Inadequate time and temperature control during initial cooking/thermal processing of food*]. Ground beef is determined to be the food vehicle and *E. coli* was the agent in this outbreak. The local outbreak is later determined to be a part of a multi-state outbreak. The primary contributing factor in this example would then be [C7: *Food contaminated by animal or environmental source before arriving at point of final preparation (pre- or post-harvest)*].
- A norovirus outbreak investigation reveals that a food worker was working while sick at a restaurant prior to illness onset of the reported cases. During the EA, investigators noted workers used their bare hands to touch foods that were not subsequently cooked, and they were not properly sanitizing food equipment. The primary contributing factor in this example would be [C9: *Contamination from infectious food worker/handler through bare hand contact with food*].

If you have any questions about how best to categorize a factor, contact CDC staff (NEARS@cdc.gov). Selecting a specific factor as the primary factor in an outbreak depends on circumstances. In some instances, it may be difficult to select only one factor as the primary factor in that outbreak. As we gain experience in implementing the concept of a primary contributing factor, we can make a determination about its usefulness and formulate better guidance.

Please note: The contributing factors have been revised and will be implemented into NEARS in January 2021. The revised contributing factors plan to be implemented into NORS in the spring of 2022. Updated guidance on the contributing factors will be released prior to implementation.

Contributing Factors

Part VII- Contributing factors: Complete this section for each identified contributing factor in this outbreak. Contributing factors are defined in the Definitions of Factors Contributing to Outbreaks section of the *NEARS Instruction Manual*.

1. Which contributing factor was identified?

Select the contributing factor identified during the outbreak investigation. Contributing factor identification should not be based on an EA alone—it should be based on all the available information gathered during the investigation, including epidemiological and laboratory information. Complete this section for each identified contributing factor.

2. In your judgment, was this the primary contributing factor for this outbreak?

- Select *Yes* if you think this was the primary contributing factor for this outbreak.
- Select *No* if you do not.

Only one primary contributing factor can be identified. See the explanation of primary contributing factor in the Primary Contributing Factor section.

3. Briefly explain why this is a contributing factor in this outbreak.

Briefly describe why this contributing factor was selected for this specific outbreak. This description should briefly describe the evidence that indicates the role of this contributing factor.

4. When did this factor most likely occur?

Select the appropriate response to indicate when the contributing factor most likely occurred. Base your answer on the EA, professional judgment, and all other information gathered about the outbreak.

- *Before vehicle entry into the food service establishment*– Select this choice if a product was contaminated before it entered the establishment. Examples include:
 - Spinach contaminated in the field or in processing arriving at the food service establishment for use (pre-harvest) or
 - Food products transported in a manner that does not ensure proper temperature control (post-harvest).
- *While the vehicle was at the food service establishment*– Select this choice if the contamination factor occurred IN the establishment. This could include any step in the establishment from the time the food is delivered until it leaves the establishment.
- *After the vehicle left the food service establishment* – Select this choice if the contamination factor occurred after the food left the establishment.

Definitions of Factors Contributing to Outbreaks

Classification

CFs are classified into 3 categories:

Contamination Factors
<ul style="list-style-type: none">• Factors that introduce or otherwise permit contamination.• Contamination factors refer to how the etiologic agent got onto or into the food.• There are 13 contamination factors, numbered C1–C13.• Contamination factors can be applicable to all etiologies.
Proliferation Factors
<ul style="list-style-type: none">• Factors that allow growth of etiologic agents.• Proliferation factors refer to how an etiologic agent was able to increase in numbers and/or produce toxic products before the food was ingested.• There are 11 proliferation factors, numbered P1–P11.• Citation of proliferation factors is only applicable in bacterial or fungal outbreaks.• Proliferation factors would not be cited in a viral outbreak.
Survival Factors
<ul style="list-style-type: none">• Factors that allow the etiologic agent to remain above an infectious dose or that fail to inactivate the contaminant.• Survival factors refer to processes or steps that should have eliminated or reduced the pathogen population to below an infectious dose but did not because of one of these factors.• There are 6 survival factors, numbered S1–S6.• Citation of survival factors is only applicable in bacterial, viral, parasitic, or fungal outbreaks.

Contamination Factors

Factors that introduce or otherwise permit contamination; contamination factors relate to how the etiologic agent got onto or into the food.

C1: Toxin or chemical agent naturally part of tissue in food**Description**

A natural toxin found in a plant, fungus, or animal;

-OR-

A chemical agent of biologic origin that occurs naturally in the plant, fungus, or animal or bioaccumulates in the plant, fungus, or animal before or soon after harvest or slaughter.

Examples

- Ciguatera fish poisoning due to consumption of tropical marine finfish which have bioaccumulated naturally-occurring ciguatera toxins through their diet
- Scombroid fish poisoning due to consumption of fish containing elevated levels of histamine. (However, if there is environmental or traceback evidence of temperature abuse, then please also identify P4 or P5, as appropriate, in addition to C1.)
- Mushroom poisoning due to consumption of toxic mushrooms

Notable Exceptions

None.

C2: Poisonous substance or infectious agent intentionally added to food to cause illness (does not include injury)**Description**

A poisonous substance, chemical agent, or infectious agent was intentionally/deliberately added to the food in quantities sufficient to cause illness. Poisons added because of sabotage, mischievous acts, and attempts to cause panic or for blackmail fall into this category. This CF does not apply to physical objects (such as a sharp object) intentionally added to food to cause injury.

Examples

- Cyanide or phenolphthalein deliberately added to food to cause illness
- Methomyl pesticide intentionally added to food to cause illness
- *Salmonella* intentionally added to food to cause illness

Notable Exceptions

None.

C3: Poisonous substance accidentally/inadvertently added to food**Description**

A poisonous substance or chemical agent was accidentally or inadvertently added to the food. This addition typically occurs at the time of preparation or packaging of the food. Misreading labels, resulting in either mistaking poisonous substances for foods or incorporating them into food mixtures, would also fall into this category.

Examples

- Sanitizer or cleaning compound accidentally added to food
- Metallic ingredient accidentally added to food (e.g., copper in cake icing)

Notable Exceptions

This does not apply to infectious agents.

C4: Ingredients toxic in large amounts accidentally added to food**Description**

An approved ingredient was accidentally added in excessive quantities to the food so as to make the food unacceptable for consumption.

Examples

- Excessive amount of niacin in bread
- Excessive amount of nitrites in cured meat
- Excessive amount of ginger powder in gingersnaps

Notable Exceptions

None.

C5: Container or equipment used to hold or convey food was made with toxic substances**Description**

The container that held or conveyed the implicated food is made of toxic substances. The toxic substance either migrates into the food or leaches into the food through contact with highly acidic foods.

Examples

- Galvanized container used to store acidic food/beverage
- Flour stored in a container that previously held toxic materials
- Pre-made ice stored in a toxic container

Notable Exceptions

This factor should not be confused with contamination resulting in a waterborne outbreak, rather than foodborne. Waterborne outbreaks generally include contamination occurring in the source water or in the treatment or distribution of water to the end consumer. For example, in drink mix/soda machines, if the water enters a contaminated machine or if there is a problem with the internal plumbing of the machine resulting in contamination (e.g., cross-connections, backflow of carbonated water resulting in copper leaching), this is a waterborne outbreak. For ice, if ice is made with contaminated water, it is also a waterborne outbreak. However, if ice is already made and then it becomes contaminated because it was previously stored in a container made with toxic substances, it is a foodborne outbreak and it would be appropriate to list C5 as a CF. For more examples and details differentiating between foodborne and waterborne outbreaks, please see NORS [Appendix A](#).

C6: Food contaminated by animal or environmental source at point of final preparation/sale**Description**

The food was contaminated at point of final preparation/sale (e.g., restaurant, private home, etc.) by animal or environmental source(s), such as from dripping, flooding, airborne contamination, access of insects or rodents, and other situations conducive to contamination.

Examples

- Mouse feces in pantry contaminates food
- A leaky roof permits water to seep into a walk-in refrigerator and contaminates stored food

Notable Exceptions

None.

C7: Food contaminated by animal or environmental source before arriving at point of final preparation (pre or post-harvest)**Description**

The food was contaminated before arriving at the point of final preparation by animal or environmental sources, either pre-harvest (e.g., growing field, harvest area, irrigation water, etc.) or post-harvest (e.g., processing or distribution facility, in warehouse storage, during transit, etc.).

Note: Traceback may implicate the identification of where the food was contaminated (pre-harvest versus post-harvest). If identified, please indicate this in the Point of Contamination question in the NORS interface; otherwise, please select “before point of final/preparation/sale: unknown”.

Examples**Pre-Harvest:**

- Shellfish from sewage polluted waters or closed beds
- Crops watered by contaminated irrigation water
- Produce grown in soil contaminated by geese
- Live poultry contaminated with *Campylobacter* then slaughtered and poultry distributed to retailers
- Eggs contaminated with *Salmonella*

Post-Harvest:

- Peanut butter contaminated by bird droppings in a processing plant
- Cheese contaminated with *Listeria* in a cheese manufacturer plant

Notable Exceptions

None.

C8: Cross-contamination of foods, excluding infectious food workers/handlers**Description**

The pathogen was transferred to the food source from contaminated surfaces, foods, and/or fomites to include, but not limited to, food worker's hands, cutting boards, preparation tables, utensils, processing lines, etc.

Examples

- A ready-to-eat (RTE) food was prepared on the same cutting board as contaminated raw poultry
- A food worker handled contaminated raw foods without subsequently washing their hands, and afterward handled an RTE food
- Materials used to clean equipment (e.g., cloths, sponges, etc.) that processed contaminated raw foods were subsequently used on surfaces that came in contact with RTE foods without first being disinfected
- Contaminated raw foods touched or dripped onto foods that were not subsequently cooked
- Contaminated raw foods were processed on shared lines with non-contaminated food items

Notable Exceptions

This CF only applies to foods that are cross-contaminated by other food or fomites, and not by an infectious food worker/handler (please indicate C9 instead).

C9: Contamination from infectious food worker/handler through bare hand contact with food**Description**

A food worker/handler, who is suspected or confirmed to be infectious, used their bare hands to touch/prepare foods that are not subsequently cooked. If it is unknown whether the food worker was wearing gloves or not, then cite C11. If there is evidence for both bare hand contact and glove-hand contact with the food, both C9 and C10 should be cited.

This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.

Potential reasons to suspect or confirm that a food worker is “infectious” — an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen:

- a) They recently displayed or admitted to common enteric disease symptoms (e.g., diarrhea, vomiting, nausea, fever) that may be similar to symptoms identified in those who are ill in the outbreak investigation
- b) Their household member exhibited similar symptoms directly preceding the outbreak
- c) They tested positive for an enteric pathogen

d) Other epidemiologic or environmental evidence.

Example

- An infectious food worker/handler preparing deli meat without wearing gloves contaminated the food served to restaurant patrons

Notable Exceptions

None.

C10: Contamination from infectious food worker/handler through glove-hand contact with food**Description**

A food worker/handler, who is suspected or confirmed to be infectious, used their glove-hands to touch/prepare foods that were not subsequently cooked. If it is unknown whether the food worker was wearing gloves or not, then cite C11. If there is evidence for both bare hand contact and glove-hand contact with the food, both C9 and C10 should be cited.

This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.

See C9 for a further description of reasons to suspect or confirm an infectious food worker/handler.

Example

- An infectious food worker/handler prepared deli meat while wearing gloves that were not changed after coughing into their hand, which contaminated the food served to restaurant patrons

Notable Exceptions

None.

C11: Contamination from infectious food worker/handler through unknown type of hand contact with food or indirect contact with food**Description**

A food worker/handler, who is suspected or confirmed to be infectious, used their hands to touch/prepare foods that were not subsequently cooked, but the epidemiologic/environmental investigation was unable to determine whether or not the food worker was wearing gloves during food preparation.

-OR-

A food worker/handler, who is suspected or confirmed to be infectious, contaminated the food indirectly (no direct bare-hand or glove-hand contact with the food).

This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.

See C9 for a further description of reasons to suspect an infectious food worker/handler.

Examples

- An infectious food worker/handler prepared deli meat, though it was unknown if gloves were worn, contaminated the food served to restaurant patrons
- An infectious food worker/handler contaminated utensils that subsequently contaminated food served to restaurant patrons.

Notable Exceptions

None.

C12: Contamination from infectious non-food worker/handler through direct or indirect contact with food**Description**

A person other than a food handler/worker who is suspected or confirmed to be infectious, contaminated ready-to-eat foods that were later consumed by other persons, resulting in spread of the illness. A “non-food handler/worker” is considered to be any person who is not directly involved in the handling or preparation of the food before service.

Potential reasons to suspect or confirm that a non-food worker is “infectious” — an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen:

- a) They recently displayed or admitted to common enteric disease symptoms (e.g., diarrhea, vomiting, nausea, fever, etc.) that may be similar to symptoms identified in those who are ill in the outbreak investigation
- b) Their household member exhibited similar symptoms directly preceding the outbreak
- c) They tested positive for an enteric pathogen
- d) Other epidemiologic or environmental evidence.

Examples

- An ill person attended an event and contaminated ready-to eat-foods in a buffet line by handling food before someone else consumed it.
- Pizza was prepared by a healthy food worker and arrived pathogen-free. An ill non-food worker, such as a mother, rearranged pizza slices onto plates before serving the slices to a group of children at a birthday party, and these children subsequently developed foodborne illness.
- An infectious non-food worker/handler contaminated utensils that subsequently contaminated food at a potluck.

Notable Exceptions

This factor should not be confused with contamination from person-to-person, rather than foodborne. For person-to-person outbreaks, there would be no association with any particular food(s).

C13: Other source of contamination (specify)**Description**

A form of contamination that does not fit into the above categories; the factor should be specified in the “Contributing Factors Comments” section.

Proliferation Factors (bacterial and fungal outbreaks only)

Factors that allow proliferation of the etiologic agents; proliferation factors relate to how the pathogen was able to increase in numbers and/or produce toxic products before the food was ingested.

P1: Allowing foods to remain out of temperature control for a prolonged period during preparation**Description**

During food preparation, food was kept out of temperature control for a prolonged period that allowed pathogenic bacteria and/or fungi to multiply to an amount sufficient to cause illness or to produce toxins if toxigenic.

Examples

- Improper thawing (such as allowing frozen food to thaw at room temperature or leaving frozen foods in standing water for prolonged periods) allowed pathogens to multiply
- Prolonged preparation time (such as prolonging preparation time by preparing too many foods at the same time) allowed pathogens to multiply

Notable Exceptions

None.

P2: Allowing foods to remain out of temperature control for a prolonged period during food service or display**Description**

During food service or display, food was kept out of temperature control for a prolonged period that allowed pathogenic bacteria and/or fungi to multiply to an amount sufficient to cause illness or to produce toxins if toxigenic.

Examples

- Left foods out at ambient temperature for a prolonged time at a church supper
- No time or temperature control measures on a buffet line

Notable Exceptions

None.

P3: Inadequate cold holding temperature due to malfunctioning refrigeration equipment**Description**

Malfunctioning refrigeration equipment caused foods to be held at an inadequate cold holding temperature.

Examples

- Walk-in cooler malfunctioned causing inadequate cold holding temperature of food
- A broken or torn door gasket caused air leakage in a reach-in refrigerator resulting in inadequate cold holding temperature of food

Notable Exceptions

None.

P4: Inadequate cold holding temperature due to an improper practice**Description**

Inadequate cold holding temperature occurred due to an improper practice.

Examples

- Overloaded refrigerator resulting in poor air circulation
- Inadequately iced salad bar
- Time/Temperature Control for Safety (TCS) foods, such as tuna or egg salad, were stacked above the fill line of the cold holding wells in a deli cold holding unit

Notable Exceptions

None.

P5: Inadequate hot holding temperature due to malfunctioning equipment**Description**

Malfunctioning hot-holding equipment caused foods to be held at an inadequate hot holding temperature.

Examples

- A steam table or crockpot broke and caused food to be held at inadequate hot holding temperatures
- **Notable Exceptions**

None.

P6: Inadequate hot holding temperature due to an improper practice**Description**

Inadequate hot holding temperature occurred due to an improper practice.

Examples

- A steam table or crockpot was not turned on or properly maintained and caused food to be held at inadequate hot holding temperatures
- A crockpot being used to heat or reheat food was overloaded and caused food to be held at inadequate hot holding temperatures
- **Notable Exceptions**

None.

P7: Improper cooling of food**Description**

Foods were refrigerated in large quantities or stored in devices where the temperature was poorly controlled and allowed pathogens to multiply.

Examples

- Foods were refrigerated in large masses or as large volumes of foods in containers, which did not allow proper cooling
- Foods were stored in containers with tight-fitting lids, pans were stacked on top of others, or crowded storage in a refrigerator, all of which led to inadequate air circulation during cooling process
- **Notable Exceptions**

None

P8: Extended refrigeration of food for an unsafe amount of time, relative to the food product and pathogen**Description**

This situation is a concern for psychrotrophic pathogenic bacteria (e.g., *Listeria monocytogenes*, *Clostridium botulinum* type E, *Yersinia enterocolitica*, *Aeromonas hydrophila*) that can multiply over sufficient time at ordinary refrigerator temperatures and grow to an amount sufficient to cause illness or produce toxins if toxigenic (e.g., *C. botulinum*).

Examples

- *Listeria* growth after refrigeration of deli meat for more than 7 days
- Kept containers of commercially prepared foods for several weeks after they were opened
- **Notable Exceptions**

None.

P9: Inadequate Reduced Oxygen Packaging (ROP) of food**Description**

Food was sealed using inadequate Reduced Oxygen Packaging (ROP) methods, which provided conditions conducive to growth of anaerobic or facultative bacteria in foods. ROP includes processing and packaging techniques that prevent the entry of oxygen into the container, such as vacuum packaging, modified or controlled atmosphere packaging, cook chill packaging, sous vide packaging, hermetically sealed containers (double seams/glass jar with lid), deep containers from which air is expressed, and products packed in oil.

Examples

- Inadequate process applied to vacuum-packed fish
- Insufficient process applied to salad in gas-flushed bag
- Ineffective hermetically seal on can
- Garlic packaged in oil with unsatisfactory process
- Lack of controlled atmosphere packaging of beef jerky
- **Notable Exceptions**

None.

P10: Inadequate non-temperature dependent processes (e.g., acidification, water activity, fermentation) applied to a food to prevent pathogens from multiplying**Description**

Non-temperature-dependent processes (e.g., acidification, water activity, fermentation) failed and allowed pathogens to multiply to an amount sufficient to cause illness. This situation is a concern for growth of preformed heat-stable toxins or bacterial spores (e.g., *Clostridium perfringens*, *Clostridium botulinum*, *Bacillus cereus*, *Staphylococcus aureus*).

Examples

- Insufficient acidification (low concentration of acidic ingredients) in home canned foods
- Insufficiently low water activity (low concentration of salt) in smoked/salted fish
- Inadequate fermentation (starter culture failure or improper fermentation conditions) in processed meat or processed cheese

Notable Exceptions

Outbreaks caused by pathogenic bacteria, including *E. coli*, *Listeria monocytogenes*, and *Salmonella* species do not usually *grow* in high-acid food, but may be able to *survive* for extended periods of time. In these cases, please cite S4.

P11: Other situations that promoted or allowed microbial growth or toxic production (specify)**Description**

A factor that promoted growth, proliferation, amplification, or concentration of bacterial agents but that did not fit into any of the other defined categories; the factor should be specified in the 'Contributing Factors Comments' section.

Survival Factors (bacterial, viral, parasitic, or fungal outbreaks only)

Factors that allow survival or fail to inactivate the contaminant; survival factors refer to processes or steps that should have killed or reduced the pathogen population to below an infectious dose but did not because of one of these factors.

S1: Inadequate time and temperature control during initial cooking/thermal processing of food**Description**

The time and temperature during initial cooking/thermal processing (e.g., pasteurizing, blanching, drying, dry roasting, frying, infrared, microwave, oil roasting, steaming) was inadequate to kill or reduce the pathogen population to below an infectious dose. In reference to cooking, but not retorting, it refers to the destruction of vegetative forms of bacteria, viruses, and parasites, but not bacterial spores. If the food under investigation was retorted, then spore-forming bacteria would be included.

Examples

- Inadequate cooking of meats/poultry before service
- Inadequate pasteurization of milk

Notable Exceptions

- Citation of S1 does not include inactivation of preformed heat-stable toxins or destruction of bacterial spores, such as *Clostridium botulinum*, unless the food underwent a retort process. If this retort process was determined to be inadequate to kill the pathogen, please cite S1. Otherwise, please cite the appropriate proliferation factor.
- Norovirus in food cannot be inactivated by moderate heat treatments, such as pasteurization. However, it can be effectively inactivated with cooking or other heat processes, such as roasting.

S2: Inadequate time and temperature during reheating of food**Description**

The time and temperature during reheating or heat processing of a previously cooked food (which may have been cooled overnight) was inadequate to kill or reduce the pathogen population to below an infectious dose.

Examples

- Reheating of sauces or roasts to a temperature insufficient to reduce the level of contamination to below an infectious dose

Notable Exceptions

Citation of S2 does not include inactivation of preformed heat-stable toxins, such as *Bacillus cereus*. Please cite the appropriate proliferation factor instead.

S3: Inadequate time and temperature control during freezing of food designed for pathogen destruction**Description**

The time and temperature during freezing was inadequate to kill or reduce the pathogen population to below an infectious dose. A freezing process may be used in order to ensure the destruction of certain parasites before raw service of some foods, such as fish.

Examples

- Pacific red snapper was not sufficiently frozen before served in raw sushi, or an investigation revealed that the time and temperature requirements to kill parasites were not achieved.

Notable Exceptions

- Some species of tuna do not harbor parasites of concern and thus freezing is not necessary. Care should be taken in determining if freezing would have been an appropriate pathogen destruction process for the fish in question before this factor is cited.
- Norovirus in food cannot be inactivated by freezing.

S4: Inadequate non-temperature dependent processes (e.g., acidification, water activity, fermentation) applied to a food to prevent pathogens from surviving

Description

Non-temperature depending processes (e.g., acidification, water activity, fermentation) designed to kill or reduce the pathogen population to below an infectious dose were inadequate or improperly used, allowing pathogens to survive. This situation is more of a concern for pathogenic bacteria with low infectious doses, making pathogen survival more often the cause for illness rather than pathogen proliferation.

Please note:

- 1) Though chemicals may be added to foods to inhibit bacterial growth, at normal levels of use, most chemicals cause inhibition rather inactivation.
- 2) Though pH is considered primarily a means of growth inhibition and not a method of destruction of existing pathogens, at low pH values, many bacterial pathogens will be destroyed if held at that pH for a significant amount of time, even if their growth is already inhibited. If the acidification procedures are inadequate, pathogenic bacteria can survive. *E. coli* O157:H7 and *Listeria monocytogenes*, in particular, are able to survive acidic conditions.

Examples

- Inadequate acidification of seafood when preparing ceviche, allowing for pathogen survival
- Inadequate acidification of unpasteurized juice, in which the inappropriately high pH allowed survival of *E. coli*
- Inadequate salting of freshwater fish, allowing for parasite survival
- Inadequate fermentation of sauerkraut, allowing for survival of *Listeria monocytogenes*
- Inadequate chlorine concentration used for washing lettuce, allowing for survival of *E. coli*.

Notable Exceptions

Norovirus in food cannot be inactivated by acidification.

S5: No attempt was made to inactivate the contaminant through initial cooking/thermal processing, freezing, or chemical processes

Description

No attempt was made to inactivate the contaminant through initial cooking/thermal processing, freezing, or chemical processes.

Examples

- Unpasteurized milk or cider
- Oysters served raw

Notable Exceptions

None.

S6: Other process failures that permit pathogen survival (specify)**Description**

A form of survival that does not fit into the above categories; the factor should be specified in the 'Contributing Factors Comments' section.

Definitions

Agent: a factor (e.g., a microorganism or chemical substance) or form of energy whose presence, excessive presence, or in the case of deficiency diseases, relative absence is essential for the occurrence of a disease or other adverse health outcome.

Commissary: A facility that prepares food for use in a food service establishment (e.g., a high school cafeteria serves as a commissary and prepares food that is shipped out to elementary and middle schools for service).

Complex Food Preparation Process: A process that requires a kill step followed by any combination of holding, cooling, reheating, and freezing. (Steps following the kill step can occur in any order.)

Complex 1: A process that includes a kill step followed by holding beyond same-day service.

Complex 2: A process that includes a kill step followed by holding and cooling (steps following the kill step can occur in any order).

Complex 3: A process that includes a kill step followed by holding, cooling, and reheating (steps following the kill step can occur in any order).

Complex 4: A process that includes a kill step followed by holding, cooling, reheating, and freezing (steps following the kill step can occur in any order).

Complex Establishment: An establishment where at least one food item prepared requires a kill step and holding beyond same day service or a kill step and some combination of holding, cooling, reheating, and freezing. The menu may include any combination of prep serve, cook serve, and complex food items.

Confirmed Vehicle: A vehicle that requires the isolation of an agent from ill persons **and** from a food **or** isolation of organisms from an epidemiologically implicated food.

Consumer Advisory: A written statement informing the customer of the potential risk associated with eating a particular food on the menu.

Contamination Factors: A factor related to how the agent got onto or into the food vehicle.

Contributing Factor: A factor that directly or indirectly caused an outbreak or likely caused an outbreak by contributing to contamination and survival of the etiologic agents or suspected agents and possibly supporting their growth or proliferation.

A contributing factor can be biological, behavioral, or attitudinal; or an element of the physical or social environment; or the result of policies related to the problem. Examples include retort, pasteurization, or cooking temperatures that do not destroy or reduce pathogens, poor personal hygiene of food workers, or cross-contamination.

Cook Serve Process: A process where the food item is prepared for same-day service and the process involves a required kill step.

Cook Serve Establishment: An establishment where at least one food item is prepared for same-day service and involves a kill step. The menu may include prep serve items or have some food on the

menu that is commercially prepared and heated for service.

Cooking: Any thermalization process that involves a kill step.

Cooler: Any type of refrigeration unit, including walk-in coolers, reach-in coolers, line cooler, etc.

Cooling: Any active process that accelerates the cooling of an ingredient, product, or food item before cold holding. Portioning does not constitute cooling for the purposes of a food flow. Portioning is described as part of a preparation process.

Critical Violation: Violations that, if left uncorrected, are more likely to contribute to contamination of food and survival and/or proliferation of pathogens, toxins, or other hazards. This also includes **priority and priority foundation violations**.

Examples of critical violations include improper cooking, cooling, and holding temperatures of foods; opportunities for cross-contamination; poor hygienic practices; and working while ill.

Violations related to dirty floors, floor drains, facility areas that need repair, lack of hair restraints, or similar violations are not considered critical violations.

Equipment: An article used in the operation of a food establishment, such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or ware washing machine.

Environmental Antecedent: A supporting factor to the contamination, survival, or increase of biological or chemical agents in food. It may be related to people, equipment, food process, food type, economics, or other circumstances. In other words, antecedents are the reason why the contributing factors occur. Antecedents are sometimes referred to as root causes of foodborne illness outbreaks.

Environmental Assessment: [see Foodborne Illness Outbreak Environmental Assessment].

Establishment: [see Food Service Establishment].

Foodborne Illness: An illness caused by consuming contaminated foods or beverages. Many pathogens can contaminate foods, so there are many foodborne illnesses. In addition, poisonous chemicals or other harmful substances can cause foodborne illnesses if they are present in food.

Foodborne Illness Outbreak: The occurrence of two or more cases of a similar illness resulting from ingestion of a common food in the United States.

Food Contact Surface: A surface of equipment or a utensil with which food normally comes into contact, or a surface of equipment or a utensil from which food may drain, drip, or splash into or onto.

Food Service Establishment: An operation that stores, prepares, packages, serves, or vends food directly to the consumer or otherwise provides food for human consumptions, such as a restaurant, school, catering business, or prison. Each establishment will have its own address, so if the business at the address changes, it becomes a different establishment. Food service establishments do not include

processing plants or establishment offering prepackaged foods that are NOT potentially hazardous.

- Chain Establishment: An establishment sharing both name and operations with other establishments. Ownership may be private, franchise, or corporate.
- Independent Establishment: An establishment with a name and operations unique to other establishments.

Food Safety Certified/Certification: A person who possesses a certificate or paper from an ANSI-accredited food safety certification program that indicates he or she passed an exam on food safety.

Food States: Description for how meat, poultry, and seafood products are received and should be processed in an establishment. There are six potential descriptions:

- Raw, non-frozen: animal or seafood proteins received in the establishment raw and unfrozen. Examples: beef, poultry, pork, etc.
- Raw, frozen: animal or seafood proteins received in the establishment raw and frozen. Examples: beef, poultry, pork, etc.
- Raw, intended for raw service: product intended for raw service (may be frozen or unfrozen). Examples: oysters or seafood used for sushi.
- Commercially processed (precooked: may require heating for palatability): commercially processed animal or seafood protein that has been precooked and does not require further cooking. Examples: various types of deli meats such as hot dogs, deli sliced ham, canned spam, etc. Also refers to commercially processed animal protein that may require heating for palatability. Examples: Fully cooked frozen fish sticks that are heated for service.
- Commercially processed (further cooking required): commercially processed animal or seafood proteins that require further cooking. Examples: chicken nuggets that are not fully cooked and require cooking before serving.
- Dried/Smoked: commercially processed animal or seafood proteins that have been dried or smoked as part of processing.
-

Food Worker: An individual working with unpackaged food, food equipment or utensils, or food-contact surfaces. This would not include wait staff or other employees who have no food handling responsibilities or who have very limited food contact, such as those adding garnish or condiments to the plate before it is served.

Freezer: Any thermally insulated unit in which the temperature is maintained at or below 32°F, including walk-in freezers, reach-in freezers, etc.

Freezing: Any process that reduces the temperature of ingredients or products to a minimum of 32°F.

- Freezing for parasite destruction: any process that involves storing an ingredient or product in a freezer at or below the temperature of -4°F for 7 days, or at -31°F or below until solid for 15 hours.
- Freezing for holding: any process that involves storing an ingredient or product at a temperature of 32°F or below.

Hazard: A biological, chemical, or physical property that may cause an unacceptable consumer health risk served.

Hazard Analysis Critical Control Point (HACCP): A systematic approach to the identification, environmental assessment, and control of food safety hazards.

Heating: Any thermalization process that does not involve a kill step. Heating refers to the heating of foods that do not have a kill step (e.g., produce) or foods for which the kill step did not occur in the establishment (e.g., commercially precooked foods).

Holding: Any process that involves temporary storage of an item after some preparation or cooking has taken place.

Holding for Service: Any process in which an item is temporarily stored after some preparation or cooking has taken place and customers will serve themselves from the holding facility (e.g., wrapped sandwiches displayed in deli cases for customers to pick up).

Incubation Period: The time interval from exposure to an infectious agent to the onset of symptoms of an infectious disease.

Jurisdiction: The area that a department or program has regulatory authority over. For food safety programs, this would be the area where staff inspect and or permit food service establishments and are responsible for conducting any types of complaint and or outbreak investigations.

Kill Step: A step in a food preparation process where raw or undercooked animal products undergo a thermalization process that reduces pathogens to a level unable to cause adverse health effects. A kill step includes freezing for parasite destruction [see **Freezing**].

Manager: A person who has overall responsibility for all or a large portion of the operation of an establishment or facility. A manager may supervise one or more employees but his or her main role is broader than just supervision.

Menu Item: A complete dish that is composed of one or more food items and can be ordered from the menu.

Meals Served: The daily average of meals from a 7-day period. Meals may be represented by ticket orders and/or customers served.

Non-Food Service Establishment: An establishment other than a restaurant or other point of final service; examples include food distribution centers, warehouses, processing plants, manufacturers, or farms.

On-the-job Training: Any sort of training conducted by the establishment or corporate office (could be peer-based). This might be anything from posting material on the wall to viewing videos to computer-based training or to sending employees to a corporate kitchen for training.

Pathogen: Any disease-producing microorganism; an agent that causes disease, especially a living

microorganism such as a bacterium or virus.

Physical Barriers: Object(s) that prevent employees from reaching the handwash sink (includes articles in, on, and around the sink that prevent handwashing).

Policies (Food Safety Policies): Food safety policies can be informal and part of on-the-job or other establishment training or they may be formal, written documents that state the policy.

Potable Water: Fresh water intended for drinking; for handling or preparing food; and for cleaning food storage and preparation areas, utensils, and equipment.

Potentially Hazardous Foods (PHF): A food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

Prep-Serve Process: A process where the food item involves no raw animal products and is prepared and served without a kill step. It may include heating commercially prepared foods for service.

Prep-Serve Establishment: An establishment with all food items prepared and served without a kill step. Some food on the menu that is commercially prepared and ready-to-eat may be heated for service. This type of establishment does not serve raw animal products (with the exception of raw oysters).

Preparation: Any process that readies an ingredient or a food item for consumption. Preparation can take place before or after the kill step or cooking step.

Primary Contributing Factor: The initial contributing factor that had it NOT occurred, the event would not have evolved into a foodborne illness outbreak. See the Part VII instructions for discussion and examples related to this term.

Primary Language: The language the person speaks most often both at work and at home.

Proliferation/Amplification Factors: These factors relate to how microbial agents are able to increase in numbers and/or produce toxic products before the vehicle is ingested.

Raw Animal Products: Animal products that have not been cooked, processed, or pasteurized; examples include unpasteurized eggs, unpasteurized dairy, uncooked meat, uncooked poultry, etc.

Raw Produce: Produce that has not been cooked or processed, such as fresh fruits and vegetables. This includes fruits and vegetables that have been washed or cleaned by removing leaves, stems, peels, rinds, etc. Examples include heads of lettuce, whole tomatoes, whole carrots, cantaloupes, potatoes, etc.

Ready-to-Eat Food: A food meets food safety standards and is edible without any further washing, cooking, or additional preparation by the food establishment or the consumer. This type of food is reasonably expected to be consumed in the current form served.

Ready-to-eat foods include the following:

- Potentially hazardous food that is unpackaged and cooked to the temperature and time required for the specific food.
- Raw, washed, cut fruits and vegetables.
- Whole, raw fruits and vegetables for consumption without further washing, such as at a buffet.
- Other food for consumption without further washing or cooking, and from which rinds, peels, husks, or shells are removed.
-

Regulatory Authority: The local, state, or federal enforcement body or authorized representative having jurisdiction over the food establishment.

Reheating: Any process that involves thermalization of a product that has been cooked (undergone a kill step), cooled, and/or cold held in the establishment. Reheating includes heating for immediate service or for hot holding of foods that have gone through a cook (kill) step in the establishment. Reheating does not include heating of commercially prepared products for palatability.

Restaurant: An establishment that prepares and serves food to customers. Restaurants do not include institutions, food carts, mobile food units, temporary food stands, restaurants in supermarkets, or caterers. Establishments that serve individual customers AND cater events are included; establishments that ONLY cater events are excluded.

Serotype: A group of intimately related microorganisms distinguished by a common set of antigens.

Survival Factors: Processes or steps that should have eliminated or reduced an agent (pathogen) but did not for the reason listed.

Suspected Vehicle: A source and mode of contamination and/or survival of etiologic agent (pathogen) in food which is consistent with the clinical symptoms, incubation, and duration of ill persons or a confirmed etiologic agent identified from ill persons. Determination can be based on statistical evidence from the epidemiological investigation, clinical evidence, compelling supportive information, or, where specific evidence is lacking, prior experience that makes it a likely vehicle.

Time/temperature Control For Safety (TCS) Food: A food that required time and temperature controls to limit pathogenic microorganism growth or toxin formation.

Utensil: A food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single-service, or single-use; gloves used in contact with food; food temperature measuring devices; and probe-type price or identification tags used in contact with food.

Vehicle: An inanimate object that can carry an agent from a reservoir to a susceptible host (e.g., food, water, blood products, and bedding).

Wiping Cloths: Cloths used for cleanup of food and non-food contact surfaces in the work area. They may be used wet or dry.

Work Area: A worker's immediate surroundings where work activities occur. The definition of work

area is subjective. To assist in defining the work area, place yourself in the employee's position and answer questions according to your observations and best professional judgment.

Whole Genome Sequencing: The laboratory method for determining detailed genetic information about pathogens. In many laboratories, this is used in place of pulsed-field gel electrophoresis, or PFGE.

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