

NORS – National Outbreak Reporting System

GUIDANCE DOCUMENT

**For reporting all waterborne (General reporting sections only)
and enteric foodborne, person-to-person, environmental,
animal contact, and unknown/indeterminate
mode of transmission outbreaks**

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This document was prepared by the NORS team.

For general questions on reporting or the guidance document, email NORSAdmin@cdc.gov.

For questions on foodborne or animal contact transmission outbreaks, email NORS-Foodborne@cdc.gov.

For questions on waterborne transmission outbreaks, email NORSWater@cdc.gov.

For questions on person-to-person transmission outbreaks, email NORSP2P@cdc.gov.

Introduction

This guidance document is intended to give detailed descriptions of each field in the NORS system. It is not intended to be a training guide on how to enter reports in NORS; for specific information on how to enter information into the fields, see the NORS training videos and guides. To review questions frequently asked about the NORS system and its functions and to find information for new NORS users, see the NORS FAQ document.

This guidance document follows the flow of the reporting forms and the web-based user interface; therefore it is recommended to view the guidance document in conjunction with the reporting forms. The headers of each section have both the name of the reporting form section and the name of the interface tab in parentheses.

See Appendix B on page 40 for information regarding NORS data requests related to the Freedom of Information Act (FOIA).

What is reportable to NORS

For NORS reporting, the definition of an outbreak is two or more cases of similar illness associated with a common exposure. Mode-specific definitions are on pages 6-7. The following can be reported to NORS:

- Outbreaks with cases in the same household should be reported.
- Single cases of foodborne botulism and foodborne toxin poisoning can be reported; however these cases will not be cleaned or analyzed for publication since they do not meet the definition of a foodborne outbreak.
- With the exception of foodborne disease outbreaks, all outbreaks can be entered into NORS regardless of the first ill date. Foodborne outbreaks on or after 1/1/2009 should be entered into NORS, while foodborne outbreaks prior to 1/1/2009 should be entered into eFORS.

Person-to-person transmission outbreaks not characterized by acute gastroenteritis, including those due to measles, Hepatitis A, influenza, pertussis, and scabies, are not reportable through NORS.

Outbreaks that span multiple years may be considered one long outbreak or multiple shorter outbreaks depending on the lag time between cases and whether an outbreak is assigned a different cluster code than an earlier outbreak. If you are uncertain about how an outbreak should be reported, or have an unusual outbreak and have questions about reporting, contact the NORS team at NORSAdmin@cdc.gov.

We are working on updating guidance for reporting multistate foodborne outbreaks and PFGE clusters—we plan to provide updates for these processes later this year to start in 2013.

Interface variables

There are a few fields listed at the top of each NORS report in the interface:

CDC Report ID

This is the unique CDC-assigned report identification number that is automatically populated by the system.

State Report ID

This is the state-assigned report identification number. It is up to the state how to number their reports. A state-assigned number cannot be used more than once in the system.

Report Status

This is the status of report. It may be active, finalized, or deleted. This is managed in the Status Admin section under the “Admin” header.

Last Status Update

This is the date that the current report status was assigned. This field is automatically updated when changes are made to the report status.

General Section (Gen-Pt1 Tab)

Author name – The username of the author of the NORS outbreak report. The author is typically the report creator unless the report has been reassigned (e.g., if the original author is no longer working at the agency). This variable is automatically populated at the time the report is created.

Report creation date – The date that the NORS outbreak report was created. This variable is automatically populated at the time the report is created.

Primary Mode of Transmission (REQUIRED FIELD)

Select the box indicating the primary mode of transmission for this outbreak. If more than one mode of transmission was implicated in the outbreak, select the mode of transmission that yielded the **first** cluster of illness that occurred during the outbreak. Once a mode of transmission is chosen in the NORS interface and the information is saved, all relevant tabs for that mode of transmission will appear.

For outbreaks where a source case (i.e., food handler) contaminates the implicated food, the source case is **not** considered part of the first cluster of illness, and the primary mode of transmission for the outbreak is considered foodborne. Similarly, if a person had a fecal or vomiting incident in recreational water and contaminated the water, which then resulted in an outbreak, this person is the source case and is not considered part of the first cluster of illness. The primary mode of transmission for the outbreak is considered waterborne. However, if the primary mode of transmission of an outbreak was person-to-person, then the source case (i.e., the case with the earliest illness onset data) **would** be considered part of the first cluster of illness.

	Person-to-person	Waterborne	Foodborne	Environmental
Source case	Include	Exclude	Exclude	Exclude

- **Food** – Select if the initial transmission of an enteric illness was associated with ingestion of a common, potentially contaminated food or beverage. A foodborne disease outbreak is defined as an incident in which two or more persons experience a similar illness resulting from the ingestion of a common food. The source case **should not** be considered part of the first cluster of illness. See Appendix A on page 39 for examples on how to choose a mode of transmission for certain beverages and foods/drinks containing ice.
 - Complete the Gen-Pt1, Gen-Pt2, Gen-Pt3, GenLab, and Food tabs.
- **Water** – Select if the initial transmission of any type of illness (enteric and otherwise) was associated with exposure via ingestion, inhalation, contact, or another route to treated or untreated recreational water, drinking water (including bottled water), water not intended for drinking or water of unknown intent. A waterborne disease outbreak is defined as two or more cases of a similar illness that are epidemiologically linked to a common water exposure. The source case **should not** be considered part of the first cluster of illness. See Appendix A on page 39 for examples on how to choose a mode of transmission for certain beverages and foods/drinks containing ice.
 - Complete the Gen-Pt1, Gen-Pt2, Gen-Pt3, Water-General, Water-Clinical Specimens (i.e., etiology) and Water tabs.

- **Animal contact** – Select if the initial transmission of an enteric illness was associated with exposure (physical contact) to farm animals, reptiles, or any other animals potentially infected with pathogens causing gastrointestinal illness in humans.
 - Complete the Gen-Pt1, Gen-Pt2, Gen-Pt3, GenLab, and Animal tabs.
- **Person-to-person** – Select if the initial transmission of an enteric illness was associated with direct contact with an infected person. These outbreaks are typically defined by two or more cases of illness in a common setting of exposure, such as a nursing home or a school. Although environmental contamination is oftentimes a factor in person-to-person outbreaks, if most of the cases had known direct contact or likely had the opportunity for direct contact with one another, consider the primary mode of transmission to be person-to-person. The source case **should** be considered part of the initial cluster of illness.
 - Complete the Gen-Pt1, Gen-Pt2, Gen-Pt3, GenLab, and P to P tabs.
- **Environmental contamination other than food/water** – Select if the initial transmission of an enteric illness was associated with exposure to a contaminated environment (i.e., contaminated environmental surface or fomite). For example, the source case vomits in a public restroom and the following day people become sick after visiting the same restroom. This would not be considered a person-to-person outbreak because those who became sick did not come into direct contact with the source case. The source case **should not** be considered part of the first cluster of illness. Although environmental contamination is oftentimes a factor in person-to-person outbreaks, if most of the cases had known direct contact or likely had the opportunity for direct contact with one another, consider the primary mode of transmission to be person-to-person rather than environmental contamination. In those cases, environmental contamination may be selected in the Mode of Secondary Transmission field, if there is evidence suggesting it contributed.
 - Complete the Gen-Pt1, Gen-Pt2, Gen-Pt3 and GenLab tabs.
- **Indeterminate/Other/Unknown** – Select if the source of initial transmission of an enteric illness was not identified, is known but not listed on the list of primary modes of transmission, or is unknown. For example, an outbreak caused by an enteric pathogen but for which there is insufficient epidemiologic data and environmental microbiology data (e.g., environmental sample test results) to link the outbreak to a specific mode of transmission would be reported as indeterminate/other/unknown.
 - Complete the Gen-Pt1, Gen-Pt2, Gen-Pt3 and GenLab tabs.

If multiple modes of transmission are involved in a given outbreak, select the primary mode that resulted in the earliest cluster of cases. For example, if an outbreak in a nursing home began with consumption of contaminated food in the dining hall and subsequently spread through person-to-person contact among residents and staff, select foodborne as the primary mode of transmission and person-to-person as the secondary mode of transmission.

For outbreaks where the mode of transmission resulting in the earliest cluster of illnesses cannot be determined, select Indeterminate/Other/Unknown as the mode of transmission, select all suspected modes of transmission in the Mode of Secondary Transmission field, and treat all outbreak-associated cases as primary cases. Report all information available and provide any additional information (e.g., exposure setting, foods involved, etc.) in the Remarks field on the Gen-Pt3 tab. For example, if there is an outbreak at a wedding and there is no way to tell if the initial exposure was from the food served or

from attendees at the wedding, select Indeterminate/Other/Unknown as the primary mode of transmission and select Food and Person-to-person as the secondary modes of transmission. Treat all cases as primary cases, with zero estimated total secondary ill.

Investigation Methods (Select all that apply)

- **Interviews only of ill persons** – Select if only ill persons were interviewed.
- **Case-control study** – This is an observational study to evaluate the relationship between an exposure (e.g., eating contaminated food; swimming in contaminated water; having direct contact with a sick person) and an outcome (e.g., illness). There are two categories of study participants, people who have the outcome of interest (cases) and people who do not have the outcome of interest (controls). Select this method if both ill persons and non-ill persons who may have had common exposures were interviewed, and this investigation method was used.
- **Cohort study** – This is an epidemiological study used to assess outcomes (e.g., the development of gastrointestinal illness) in a group/cohort of people. Study participants are observed over time or counted to determine how many people experience the outcome of interest, and when the outcome occurred. Members in a cohort are defined according to their exposure profile (e.g., an exposed group and an unexposed group). In outbreak investigations, a cohort is frequently defined by membership in an organization (e.g., a boy scout troop attending a weeklong camp). Select this method if this investigation method was completed.
- **Food preparation review** – Select if a review of the preparation practices associated with the implicated food were conducted.
- **Water system assessment: Drinking water** – Select if the environmental health investigation included an assessment of a drinking water system.
- **Water system assessment: Nonpotable water** – Select if the environmental health investigation included an assessment of a nonpotable water system (e.g., cooling tower, irrigation system).
- **Treated or untreated recreational water venue assessment** – Select if the environmental health investigation included an assessment of one or more treated or untreated recreational water source (e.g., swimming pool, lake, etc.).
- **Investigation at factory/production/treatment plant** – Select if a factory, production, or treatment plant was investigated (e.g., poultry processing plant, water treatment facility, etc.).
- **Investigation at original source (e.g., farm, water source, etc.)** – Select if the original source of implicated food or water vehicle was investigated (e.g., the poultry farm, lake, well, etc.).
- **Food product or bottled water traceback** – Select if a traceback of the implicated food, beverage or bottled water was conducted.
- **Environment/food/water sample testing** – Select if samples were taken from the environment, food, or water for testing.
- **Other** – Select if investigated method is not listed above, and provide additional investigation methods in the comment section below (e.g., third party data collection).

Comments: Enter any additional information relevant to the investigation methods for the outbreak

Dates (mm/dd/yyyy)

The following dates refer to **primary cases** that resulted from the mode of transmission selected above.

- **Date first case became ill (REQUIRED FIELD)** – Indicate the date the first case became ill. For foodborne disease outbreaks, the date must be on or after 01/01/2009. For all other outbreak modes there is no date restriction. If no date is selected, the report will be saved with the default date of 01/01/1950.
- **Date last case became ill** – Indicate the date the last case became ill. If the date is unknown, leave this field blank.
- **Date of initial exposure** – Indicate the date when the initial known exposure took place among primary cases. If the initial exposure date is unknown, leave this date field blank. If the first known exposure date is not the true initial exposure date, leave this field blank and provide the first known exposure date in the Remarks field under the Gen-Pt3 tab.
- **Date of last exposure** – Indicate the date when the last known exposure took place among primary cases. If the last exposure date is unknown, leave this date field blank. If the last known exposure date is not the true last exposure date, leave this field blank and provide the last known exposure date in the Remarks field under the Gen-Pt3 tab.
- **Date of report to CDC (other than this form)** – If CDC was contacted before completing the outbreak report (via telephone, e-mail, fax, etc.), enter the date of initial contact with CDC about this outbreak.
- **Date of notification to State/Territory or Local/Tribal Health Authorities** – Enter the date that state/territory or local/tribal health authorities were first notified or first learned about the outbreak.

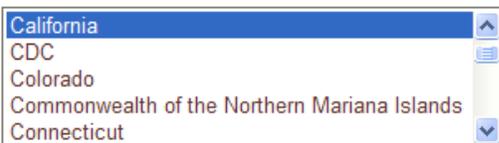
Geographic Location

The following section refers only to primary cases that resulted from the mode of transmission selected above.

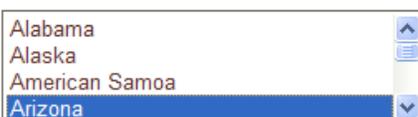
- **Reporting state (REQUIRED FIELD)** – Select the name of the state that is reporting the outbreak. This field will be auto-populated based on the reporting site affiliation of the report author.
- **Exposure occurred in multiple states** – Indicate if outbreak resulted from exposure that occurred in multiple states.
 - **Definition of a multistate outbreak for foodborne and waterborne disease outbreaks** – A multistate outbreak is defined as the occurrence of two or more cases of a similar illness resulting from **exposure to a common source**, where exposure occurred in **more than one state** (e.g., product from manufacturer X that was distributed to two or more states). States involved in a multi-state foodborne outbreak should create one outbreak report for their state, even if they only have one case. For additional guidance, see the Guidelines for Reporting Foodborne Multistate Exposure Outbreaks in NORS.
 - If entering a multistate outbreak, check the box for **Exposure occurred in multiple states** so that CDC can include the report in a final, comprehensive multistate outbreak report.

- **Other states:** Select the other states involved in the outbreak. For example, if an outbreak was reported by California but the outbreak exposure occurred in both California and Arizona, the report would look like this:

Geographic Location

Reporting State: 

- Exposure occurred in multiple states
- Exposure occurred in a single state, but cases resided in multiple states

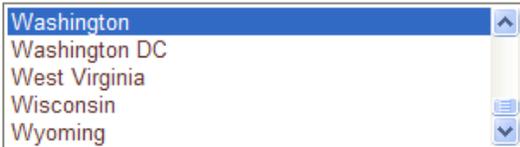
Other States: 

Note: An outbreak where the exposure occurred in multiple states and a common exposure was determined, as described above, would be considered a multistate outbreak and consolidated by someone at CDC. However, if the possible exposure occurred in multiple states, but a common exposure was not identified, this is not considered a multistate outbreak (e.g., PFGE cluster is reported and investigation does not yield a common food or water vehicle). States should enter these as individual state reports and indicate any exposure that occurred in other states in NORS. If there is strong evidence of a possible common exposure these reports may be consolidated by CDC.

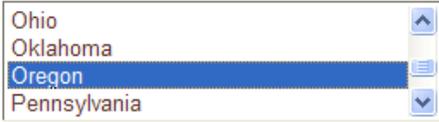
We understand that states may receive notification from the state laboratory regarding a cluster of cases with matching PFGE patterns. These clusters may be sporadic cases or true outbreaks. If the cluster is believed to be an outbreak and is not already reported in NORS, please enter a new NORS report for the outbreak. However, if the cluster is believed to be a sporadic event, this should not be entered into the system.

- **Exposure occurred in a single state, but cases resided in multiple states** – If an exposure occurred in a single state, but cases resided in multiple states, the outbreak is not considered a multi-state outbreak. Check the box labeled “Exposure occurred in a single state, but cases resided in multiple states”. **The state in which the exposure occurred is the one that should report the outbreak.** Other states that have cases associated with the outbreak should send the information to the reporting state for inclusion in the NORS report. For example, residents from New York, Pennsylvania, and Florida attended an event in New York and became ill from an exposure at the event. As a similar example, residents from multiple states traveled to a waterpark in another state and became ill from using a wave pool. If you need assistance in contacting other states, please email us at NORSAdmin@cdc.gov.
 - **Other states:** Select the other states involved in the outbreak. For example, if Washington had an outbreak exposure occur in their state and reported it but outbreak cases resided in both Washington and Oregon, the report would look like this:

Geographic Location

Reporting State: 

- Exposure occurred in multiple states
- Exposure occurred in a single state, but cases resided in multiple states

Other States: 

- **Reporting county** – Indicate the name of the county reporting the outbreak. The county in which the exposure occurred is the one that should be listed as the reporting county.
- **Exposure occurred in multiple counties in reporting state** – Indicate if the outbreak resulted from an exposure that occurred in multiple counties.
 - **Other counties:** Select the other counties involved in the outbreak.
- **Exposure occurred in a single county, but cases resided in multiple counties** – Indicate if exposure occurred in a single county but ill persons were residents of multiple counties. For example, residents from Fulton, Clayton, and DeKalb Counties in Georgia attended an event in Fulton County and became ill from an exposure at the event.
 - **Other counties:** Select the other counties involved in the outbreak.
- **City/Town/Place of exposure** – Enter city, town, or place of exposure. DO NOT include proprietary information, private facility names, or physical addresses. If necessary, report such information in the Remarks field under the Gen-Pt3 tab. For example, if the reporting state was Georgia and the reporting county was Fulton, City/Town/Place of exposure might be one or more cities/towns incorporated into Fulton County, such as Alpharetta or Johns Creek.

General Section (Gen-Pt2 Tab)

Number of Primary Cases

Only include data for primary cases in this section. Usually, primary cases and secondary cases differ by mode of transmission (e.g., in a foodborne outbreak that is followed by person-to-person transmission to household contacts, the household contacts are secondary cases). However, **person-to-person** outbreaks may also occur where primary and secondary cases share the same mode of transmission (i.e., both result from person-to-person transmission), but have different exposure contexts. For example, a person-to-person outbreak in a nursing home may result in primary cases among residents and staff and secondary cases in household contacts. Any household contacts that became ill from person-to-person transmission would be considered secondary cases even though the primary and secondary modes of transmission were the same.

Secondary cases should be recorded in the Secondary Cases section of the Gen-Pt3 tab. For outbreaks where multiple modes of transmission or exposures are suspected but cannot be separated from one another, classify all cases as primary cases. In such instances, report suspected transmission modes and other details in Gen-Pt3 tab: Secondary Cases even if the number of secondary cases is reported as zero, and report additional information such as exposure settings in the Remarks field. Refer to the bottom of page 7 for more information.

- **Lab-confirmed primary cases** – Primary cases in which a specimen was collected and a laboratory was able to confirm the pathogen(s) or agent(s) causing illness. Marine toxin cases that meet exposure and symptom confirmation guidelines should be included in this count. For a foodborne outbreak, the source case such as the food handler who was lab confirmed should not be included in this count.
- **Probable primary cases** – Primary cases that are epidemiologically linked to a confirmed case or setting but do not have laboratory confirmation (e.g., a specimen was not collected or submitted to a laboratory). For a foodborne outbreak, the source case such as the ill food should not be included in this count.
- **Estimated total primary ill (REQUIRED FIELD)** – Enter the total estimated primary cases, including lab-confirmed and probable, using the outbreak-specific definition. The estimated total primary ill should be **greater than or equal to** the sum of the lab-confirmed and probable primary cases.

Note: The Lab-confirmed primary cases, Probable primary cases, and Estimated total primary ill fields are not intended to conflict with a state's outbreak-specific case definition, but rather are intended to determine which outbreaks have included laboratory confirmation and which have not. The remainder of the Primary Cases section is based on the number of estimated total primary ill.

Example 1: In an outbreak of *Cryptosporidium*, the state's case definition for this outbreak is as follows: A confirmed case was defined as a person who swam in the community pool with an illness onset date on or after September 1, 2008. The state reported 10 cases that met this case definition. Of these 10 cases, 2 cases were lab-confirmed cryptosporidiosis.

Therefore, for NORS reporting purposes:

Lab-confirmed primary cases	2
Probable primary cases	8
Estimated total primary ill	10

Example 2: In an outbreak of scombroid toxin, 5 restaurant patrons reported a tingling and burning sensation on their tongues and throats after eating tuna. Laboratory testing was not done.

Therefore, for NORS reporting purposes:

Lab-confirmed primary cases	5
Probable primary cases	Blank
Estimated total primary ill	5

Example 3: In an outbreak of unknown etiology, 12 people reported becoming ill after consuming hamburgers at a banquet. Laboratory testing was inconclusive.

Therefore, for NORS reporting purposes all suspected illnesses can be placed in the Probable primary cases field (12) and 0 entered in the Lab-confirmed primary cases field:

Lab-confirmed primary cases	0
Probable primary cases	12
Estimated total primary ill	12

Primary Case Outcomes

Number of Primary Cases (these categories are not mutually exclusive)

- **Died** – Indicate the number of cases who died as a result of becoming ill during the outbreak. Do not leave this field blank. If there were no deaths, enter 0 and indicate the total number of cases for whom information is available in the appropriate box. If a case was hospitalized with an unrelated illness, became ill with the outbreak-related pathogen, and then died due to the outbreak pathogen, they should be included in this count. Neonatal deaths should be included in this count. Fetal loss should not be included in this count, but these should be noted in the Remarks field in the Gen-Pt3 tab.
- **Hospitalized** – Indicate the number of cases that were hospitalized as a result of becoming ill during the outbreak.
- **Visited ER** – Indicate the number of cases who visited the emergency room or department as a result of becoming ill during the outbreak.
- **Visited health care provider (excluding ER visits)** – Indicate the number of cases who visited any kind of **outpatient** health care provider, including primary care physicians, physician’s assistants,

nurses, or other medical professionals, or urgent care facilities, as a result of becoming ill during the outbreak. Do not include ER visits or hospitalizations in this field.

Number With Info Available (primary cases only)

- **Died** – Indicate the total number of cases for whom information on survival status is available.
- **Hospitalized** – Indicate the total number of cases for whom information on hospitalization status is available.
- **Visited ER** – Indicate the total number of cases for whom information on emergency room or department visits is available.
- **Visited health care provider (excluding ER visits)** – Indicate the total number of cases for whom information on outpatient health care provider visits is available, excluding those who visited an ER.

Sex (number or percent of primary cases)

Enter the number or percent of males and females among the total number of primary cases for whom information is available. The numbers should add up to the number of estimated total ill and percents should add up to 100. If you have percents that add up to a number other than 100 (e.g., 99), then case counts should be entered instead.

Age (number or percent of the primary cases)

Enter the number or percent that falls into each age group among the total number of primary cases for whom information is available. The numbers should add up to the number of estimated total ill and percents should add up to 100. If you have percents that add up to a number other than 100 (e.g., 99), then case counts should be entered instead.

Incubation Period

The incubation period is the time between the implicated exposure and the clinical onset of illness for primary cases, and includes both the date/time of exposure through the date/time that the symptoms began. For example, if cases ingested contaminated beef on Monday, May 1 and diarrhea started Friday, May 5, the incubation period would be 4 days.

Indicate the shortest, median, and longest incubation period, and the total number of primary cases for whom information is available. If sufficient data is not available to calculate a particular range, leave that range blank. In addition, select the appropriate units (minutes, hours, or days).

If information is only available for one case, then enter the same information for the shortest, median, and longest incubation periods.

If the incubation period is unknown, check the box labeled “Unknown incubation period”.

Duration of Illness (among recovered cases)

The duration of illness is the time between the onset of the earliest symptom to the time the last symptom ended, and includes both the date/time that symptoms began through the date/time that the symptoms ended. For example, a case had episodes of diarrhea that started on Monday, March 4 and vomiting that started on Tuesday, March 5. The diarrhea ended on Wednesday, March 6, but vomiting continued until Thursday, March 7, so the duration of illness would be 4 days (March 4–7).

Indicate the shortest, longest and median duration of illness, and the total number of primary cases for whom information is available among those who have recovered. If sufficient data is not available to calculate a particular range, leave that range blank. In addition, select the appropriate units (minutes, hours, or days).

If information is only available for one case, then enter the same information for the shortest, median, and longest durations of illness.

If duration of illness is unknown, check the box labeled “Unknown duration of illness”.

Signs or Symptoms

The following signs, symptoms and outcomes refer **only to primary cases** that resulted from the primary mode of transmission. Enter the number of cases for whom specific symptom information is known. The symptoms of the source case such as the ill food handler should not be included in this count.

- **Symptom** – This is the name of the symptom. If the symptom is not in the list already provided, add it to the list. Each symptom has a unique ID number that users cannot see; duplicate symptoms or multiple spellings of a symptom (e.g., vomits or vomiting) may make it difficult to use that symptom in future data analyses and might be confusing to other NORS users. Therefore, before entering a new symptom, please double-check to make sure it is not already included in the list.
- **# cases with signs or symptoms** – For each symptom reported, enter the number of primary cases with that symptom during the outbreak. If the number of cases is entered for a symptom, the number of cases with information available must also be entered.
- **# of cases with information available** – For each symptom reported, enter the number of primary cases for whom information is available on whether they experienced that particular symptom during the outbreak. This number may be as few as the number of primary cases with that symptom or as great as the total number of primary cases.

Note: If *Escherichia coli*, Shiga toxin-producing is the outbreak etiology, enter all available data for the symptom hemolytic uremic syndrome (HUS).

- If no cases reported HUS, enter zero for ‘# Cases with signs or symptoms’ and enter the number of cases with information about that symptom for the ‘Total number of cases for whom information was available’
- If only some of the cases have information about HUS, enter the number of cases who has the symptom for ‘# Cases with signs or symptoms’ and enter the number of cases with information about that symptom for the ‘Total number of cases for whom information was available’
- For example, of the six cases of *E. coli*, Shiga toxin-producing only four had information on if they had HUS and only two cases reported they had HUS.
 - ‘# Cases with signs or symptoms’= 2 and ‘Total number of cases for whom information was available’= 4.
- For example, four cases of *E. coli*, Shiga toxin-producing all had information on if they had HUS. One case reported HUS and three said that they did not have HUS:
 - ‘# Cases with signs or symptoms’= 1 and ‘Total number of cases for whom information was available’= 4.

General Section (Gen-Pt3 Tab)

Secondary Cases

A secondary case is one in which the person was not directly exposed to the food, water, animal(s), person(s) or environment that was implicated in the initial outbreak but had another exposure that led to illness (most commonly, person-to-person contact with a primary case). Usually primary cases and secondary cases differ by mode of transmission (e.g., in a foodborne outbreak that is followed by person-to-person transmission to household contacts, the household contacts are secondary cases). However, person-to-person outbreaks may also occur in which primary and secondary cases share the same mode of transmission (i.e., both result from person-to-person transmission) but have different exposure contexts. For example, a person-to-person outbreak in a nursing home may result in primary cases among residents and staff and additional cases in household contacts. Any household contacts that became ill from person-to-person transmission would be secondary cases, even though the primary and secondary modes of transmission were the same.

Any cases that can be clearly defined as secondary cases using the definitions described above should be detailed in the Secondary Cases section of the Gen-Pt3 tab. For outbreaks where multiple modes of transmission or exposures are suspected but cannot be separated from one another, classify all cases as primary cases. In such instances, report suspected transmission modes and other details in Gen-Pt3 tab: Secondary Cases even if no numbers for secondary cases are being reported, and report additional information such as exposure settings in the Remarks field.

Mode of Secondary Transmission (Select all that apply)

This field refers only to secondary mode of transmission. If more than one mode of transmission was involved during the outbreak, the secondary mode of transmission would yield the second cluster of illness in the outbreak. Select all that apply.

- **Food** – Select if secondary transmission of illness was associated with ingestion of a common, potentially contaminated food/beverage item.
- **Water** – Select if secondary transmission of illness was associated with exposure via ingestion, inhalation, contact, or another route to treated or untreated recreational water, drinking water (including bottled water), water not intended for drinking or water of unknown intent.

Note: See Appendix A on page 39 for examples on how to choose a mode of transmission for certain beverages and foods/drinks containing ice.

- **Animal contact** – Select if secondary transmission of illness was associated with exposure (physical contact) to farm animals, reptiles, or any other animals potentially infected with pathogens causing gastrointestinal illness in humans.
- **Person-to-person** – Select if secondary transmission of illness was associated with direct contact with an infected person. Secondary person-to-person cases are those exposed directly to primary cases that became infected through the primary mode of transmission. For example, an outbreak of norovirus occurred after a catered meal with subsequent transmission occurring in family members of attendees. The primary mode of transmission would be foodborne, and the secondary mode of transmission would be person-to-person. Note that a primary person-to-person outbreak consists of multiple generations of exposures and cases, all of which may be involved in the same

exposure context (e.g., illness spread among residents and staff of a nursing home). In this case all of the residents and staff that became ill would be considered primary cases and only those that became ill through a different exposure context (e.g., household contacts of ill staff members) would be considered secondary cases.

- **Environmental contamination other than food/water** – Select if secondary transmission of illness was associated with an environmental contaminant. For example, consider an outbreak of norovirus that occurred after consumption of a contaminated catered meal at a conference center. A primary case, who had consumed the contaminated food the day prior, vomited in a public restroom in the conference center, and other users of that restroom who did not have direct contact with the primary case and did not attend the catered meal subsequently became ill. The primary mode of transmission would be foodborne, and the secondary mode of transmission would be environmental contamination.
- **Indeterminate/Other/Unknown** – Select if the source of secondary transmission of illness was not identified, is known but not listed on the list of modes of transmission, or is unknown.

Number of Secondary Cases

Only include information on secondary cases; information on the primary cases should be completed in the Gen-Pt2 Tab: Number of Primary Cases section.

- **Lab-confirmed secondary cases** – Enter the number of secondary cases associated with the outbreak in which a specimen was collected and a laboratory was able to confirm the pathogen(s) or agent(s) responsible for the case of illness.
- **Probable secondary cases** – Enter the number of secondary cases that are suspected of being associated with the outbreak but do not have laboratory confirmation (e.g., a specimen was not collected or submitted to a laboratory).
- **Estimated total secondary ill** – Enter the total estimated secondary cases, including lab-confirmed and probable, using the outbreak-specific definition.
- **Total # of cases (Primary + Secondary)** – This field will auto-populate to include all primary and secondary cases.

EHS

This field is used to link outbreak investigation reports to environmental investigations. If one or more Environmental Health Specialist-Network (EHS-Net) reports contain outbreak-specific information, enter the report ID(s) into the fields provided.

Traceback

A traceback is conducted by local, state, and/or federal authorities to determine where contaminated food or bottled water came from, as far back to its origin or source as possible. Indicate if a traceback was attempted, regardless of its success.

- **Source Name (if made publicly available by regulatory agency and/or the company)** – Enter where the contaminated food or bottled water came from. Examples would be the name of a grocery store, a specific farm or ranch, etc. If the source name has not been made publicly available, DO NOT include proprietary information, private facility names, or physical addresses.

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- **Source Type** – Enter facility where food or bottled water came from. For example, a poultry farm, tomato-processing plant, bottled water factory, etc.
- **Location of source** – Enter **State** (or if not in the United States, the area, province, or region), and **Country** from which the contaminated food or bottled water came.
- **Comments** – Enter the agency that conducted the traceback and any additional comment(s) pertaining to the information found in the traceback.

Recall

- **Check if any food or water product was recalled** – If any foods or bottled water involved in the outbreak were recalled, check the box provided.
- **Type of item recalled** – Enter in a general description of the type of item recalled (e.g., peanut butter).
- **Comments** – Enter in any additional information about the recall in the text box provided (e.g., brand and lot numbers for the recalled item).

Reporting Agency

This section auto-populates to show the agency name, the agency contact's name, title, phone number, e-mail address, and fax number associated with that outbreak report. The contact name listed is not necessarily the same as the author of the report.

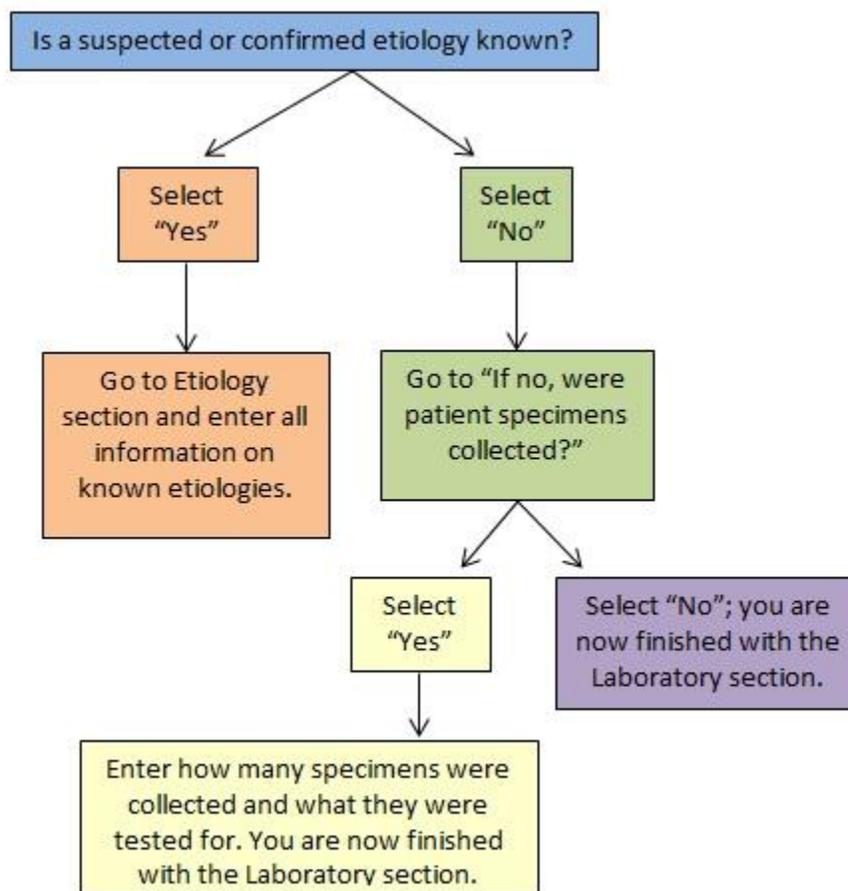
Remarks

Briefly describe important aspects of the outbreak, including dates, not covered elsewhere in the NORS report. For reports in which the mode of transmission is environmental contamination or unknown/indeterminate/other, please include the outbreak setting. Indicate if any adverse outcomes occurred in special populations (e.g., pregnant women, immunocompromised persons). NORS encourages states to attach any documents that provide additional information to the outbreak report under the Attach Tab. See page 23 for details.

Laboratory Section (GenLab Tab)

Note: this section pertains **only to primary cases**. Do not enter any information concerning specimen collection or laboratory testing of secondary case samples. We accept both suspected and confirmed etiologies in this section.

- **Etiology known?** – If etiology is known (either confirmed or suspected), select “Yes”, **SKIP the specimen collection questions below**, and move on to the “Etiology” section. If there is not a confirmed or suspected etiology, select “No” and answer the following questions:
 - **If no, were patient specimens collected?** – If there is not a confirmed or suspected etiology for the outbreak, indicate whether or not any patient specimens were collected from primary cases. Do not include any environmental or food specimens. Omit foodhandler specimens if the outbreak is foodborne transmission.
 - **If yes, how many specimens were collected?** – If any patient specimens were collected from an outbreak of unknown etiology, indicate how many specimens were collected.
 - **What were they tested for?** - If patient specimens were collected from an outbreak of unknown etiology, indicate whether the specimens were tested for bacteria, chemicals or toxins, viruses, and/or parasites. Select all that apply.



For example, if the outbreak etiology is unknown and two patient specimens were tested for bacteria, it would be reported like this:

Gen-Pt1 Gen-Pt2 Gen-Pt3 GenLab Attach

Food

Etiology known? Yes No

if no, were patient specimens collected? Yes No Unknown

If yes, how many specimens were collected? 2

What were they tested for?

- Bacteria
- Chemicals/Toxins
- Viruses
- Parasites

Save Form

Etiology

Enter the name of the bacteria, virus(es), parasite(s), and/or chemical/toxin(s) known or suspected to be responsible for the outbreak. If available, include the serotype and other characteristics such as phage type, virulence factors, and metabolic profile. Confirmation criteria are available at http://www.cdc.gov/outbreaknet/references_resources/guide_confirming_diagnosis.html or MMWR2000/Vol. 49/SS-1/App. B.

Note: Waterborne disease outbreak reports have a separate tab for reporting etiology. Additional guidance on confirmed vs. unconfirmed etiologies in waterborne disease outbreaks is included under the NORS-Water Clinical Specimens tab.

- **Genus** – For each suspected and confirmed etiology, list the genus name; chemicals/toxins are listed in this category. If the correct genus is not listed in the drop-down, select “Other bacterial”, “Other viral”, “Other parasitic”, or “Other chemical” as appropriate and then specify the etiology in the “Other Characteristics” field. For norovirus outbreaks, select “Calicivirus” as the genus and “norovirus” as the species name.
- **Species** – For each suspected and confirmed etiology, select the appropriate species name. If more than one species of a single genus is involved in an outbreak (e.g., both *Shigella sonnei* and *Shigella flexneri*), enter each one as a separate etiology.
- **Serotype** – For each suspected and confirmed etiology, list the serotype, if known. Make sure to provide serotype for all *Escherichia coli*, Shiga toxin-producing (STEC), and *Salmonella enterica* outbreaks. If more than one serotype of a single species is involved in an outbreak, enter each one as a separate etiology. For norovirus, select the genogroup (GI or GII) and the specific genotype (e.g., GII_4 New Orleans (2009)) if that level of detail is available. If molecular sequencing was not performed, select either “Genogroup I (GI), not sequenced” or “Genogroup II (GII), not sequenced” based on the real-time RT-PCR results.
- **Confirmed** – Check this box only if the etiology listed is the confirmed etiology for the outbreak. You may enter multiple confirmed etiologies. For specific pathogen confirmation guidelines, visit

the Outbreak Response guide located here: [CDC - Guide to Confirming a Diagnosis in Foodborne Disease - OutbreakNet Team](#).

- **Other characteristics** – List any other pertinent characteristics of the outbreak etiology. For example, additional serotype information which may not be captured elsewhere.
- **Detected in** – Indicate whether the etiology listed was detected in: 1) patient specimen, 2) food specimen, 3) environmental specimen, and/or 4) food worker specimen. Multiple selections are permitted. Select ‘detected in’ for both suspected and confirmed etiology outbreaks.
- **# of lab-confirmed cases** – Indicate the number of laboratory-confirmed primary cases associated with each etiology reported.

Note: For most etiologic agents reported here, CDC considers an outbreak to have a confirmed etiology if there are two or more lab-confirmed cases. However, because outbreaks of botulism, marine toxins, and other chemical outbreaks have such distinct clinical symptoms, a physician's diagnosis is often sufficient and laboratory confirmation is not always necessary to classify an outbreak as having a confirmed etiology. Therefore, for such outbreaks, CDC would consider the etiology confirmed if there are at least 2 cases (lab confirmed and/or probable cases) with signs and symptoms meeting the confirmation criteria. Lab confirmed foodworker cases can be included in this count. For such outbreaks, indicate ‘Yes’ in the ‘Confirmed outbreak etiology’ variable of the Etiology section.

Example 1: In a botulism outbreak, there was 1 case in which laboratory testing indicated a positive test for botulism, and there were 5 cases in which laboratory tests were not completed, but the cases displayed symptoms and exposures consistent with a botulism infection.

For NORS reporting, indicate in the Gen Pt-1 Tab: Number of Primary Cases:

Lab-confirmed primary cases	1
Probable primary cases	5
Estimated total primary ill	6

AND

In the GenLab Tab: Etiology

Genus	Species	Serotype	Confirmed outbreak etiology	Other characteristics	Detected in*	# Lab-confirmed cases
<i>Clostridium</i>	<i>botulinum</i>		<input checked="" type="checkbox"/> yes		1 – patient specimen	1

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Visit http://www.cdc.gov/outbreaknet/references_resources/guide_confirming_diagnosis.html for additional confirmation criteria for botulism, marine toxins and other chemical outbreaks.

Isolates

For bacterial pathogens, provide representative laboratory data for each distinct pattern. For viral pathogens (norovirus and sapovirus), provide CaliciNet outbreak code, key and genotype for each distinct strain identified in the outbreak. Enter at least three isolates for foodborne outbreaks with the information that is available. If you do not have three isolates, enter “N/A” or “Unavailable” under “State Lab ID” or “CDC PulseNet or CaliciNet Outbreak Code” for the missing isolates.

- **State Lab ID** – Provide the state-assigned laboratory isolate identification number.
- **CDC PulseNet or CaliciNet outbreak code** – Indicate the PulseNet outbreak cluster code or CaliciNet outbreak number for bacterial and viral pathogens, respectively. This field is very important for distinguishing outbreak-associated cases from other sporadic cases and for outbreaks involving more than one state.
 - A PulseNet outbreak cluster code will have four numbers that make up the year and month of the cluster, two characters that represent the lab ID, three letters that are the serotype code, a dash, and then a unique cluster number (e.g., 0902MLJPX-4).
 - The CaliciNet outbreak number (CaliciOBNumber) is assigned by CDC when a submission is made through CaliciNet and consists of the four digit year, the letters “OB”, and a three digit sequential number (e.g., 2011-OB-458).
- **CDC PulseNet pattern designation for enzyme 1** – Indicate the PulseNet pattern/PFGE pattern for the first enzyme.
- **CDC PulseNet pattern designation for enzyme 2** – Indicate the PulseNet pattern/PFGE pattern for the second enzyme.
- **CaliciNet Key/Other molecular designation 1** – Indicate the CaliciNet key for outbreaks entered into CaliciNet or any other molecular information related to this outbreak (e.g., MLVA). The CaliciNet key is generated by the testing laboratory and consists of the four digit year, the letters “SP”, and a four digit sequential number (e.g., 2011-SP-0654).
- **CaliciNet Genotype/Other molecular designation 2** – Indicate the CaliciNet genotype for outbreaks entered into CaliciNet or any other molecular information related to this outbreak (e.g., MLVA).

For information related to PulseNet, visit the following webpage:

<http://www.cdc.gov/pulsenet/index.htm>.

Attachments (Attach Tab)

CDC encourages states to attach any documents that provide additional information to the outbreak report. Examples of possible documents to attach are unpublished agency reports, Epi-Aid reports, publications, etc. The information in these documents can be particularly helpful to outbreak coordinators who were not involved in the outbreak. The maximum allowable file size for a NORS outbreak report in the interface is 1MB for each attachment. If you would like to decrease the file size of a particular document there are a number of ways to do so. If the file is a PDF, you can go to the Document tab on the menu bar in Adobe Acrobat and select "Reduce File Size". Another option is to send one or multiple files to a compressed (zipped) file by highlighting and right clicking on the file(s) in which you would like to reduce the size. If you continue to have issues with attaching a file, contact us at NORSAdmin@cdc.gov. Additional documents can be attached to a report as they become available.

Person-to-person (P to P Tab)

Only complete this section if person-to-person was identified as the primary mode of transmission.

Major setting of exposure

Choose only one major setting of exposure for the person-to-person outbreak. If there was more than one setting of exposure, indicate the major setting of exposure that yielded the first cluster of illness in the outbreak. If the major setting of exposure is not included in the list provided, users may enter their own setting name. However, duplicate settings or multiple spellings of a setting (e.g., Adult day care and adult daycare) may make it difficult to use that setting in future data analyses and might be confusing to other NORS users. Therefore, before entering a new setting, please double-check the list provided and use the auto-complete feature to make sure your setting has not already been entered.

- **Camp** – Indicate if exposure occurred in a day camp or overnight camp designed to provide simple group accommodations and organized recreation or instruction for school-age children, such as a Boy or Girl Scout camp, Bible camp, tennis camp, summer camp, etc.
- **Child daycare** – Indicate if exposure occurred in a facility designed to care for children during the day when not in school. This also includes daycare based in a residential home.
- **Community-wide** – Indicate if exposure was community-wide and if the first cluster of illness was not clearly based in one particular setting within the community. For community-wide exposures, consider all exposed and ill persons to be residents in the Attack Rates section.
- **Hospital** – Indicate if exposure occurred in a hospital, i.e., if illness was acquired through nosocomial infection. This does not include illnesses acquired in another setting or dispersed throughout the community, but recognized through hospital admission of a cluster of illnesses.
- **Hotel** – Indicate if exposure occurred at an establishment that provides lodging and offers services such as meeting rooms for conferences/conventions, common areas for guests, etc. Motels, rented cabins, hostels, etc. should be considered a hotel when indicating the setting of exposure. Use this setting of exposure for person-to-person transmission outbreaks occurring at conferences and conventions (e.g., a convention center).
- **Long-term care facility (Nursing home)** – Indicate if exposure occurred in a facility designed to provide long-term care for the elderly or the disabled. Nursing homes, assisted living facilities, adult day care facilities, community-based residential facilities and other long-term care facilities which may not necessarily provide skilled nursing care should all be considered a long-term care facility when indicating the setting of exposure. The specific type of long-term care facility may be entered in the Remarks field.
- **Prison or detention facility** – Indicate if exposure occurred in a prison, jail, juvenile detention center, or similar detention facility.
- **Private setting (residential home)** – Indicate if exposure occurred in a private residence.
- **Religious facility** – Indicate if exposure occurred in a religious facility such as a church, temple, or other facility designed to house religious meetings.
- **Restaurant** – Indicate if exposure occurred in any establishment designed to provide meals for paying customers.

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- **School** – Indicate if exposure occurred in a school setting, such as a university, college, kindergarten, grade school, or summer school. This includes residential facilities at schools (i.e., dormitories).
- **Ship** – Indicate if exposure occurred on any commercial ship where passengers stay at least one night, such as a cruise ship.
- **Workplace** – Indicate if exposure occurred in a workplace other than setting of exposures listed above, such as an office building. Consider all persons exposed and/or ill as residents/guests.

Attack rates for major settings of exposure

For the major setting of exposure, estimate the total number of persons likely exposed in that setting and the total number of persons ill for each of the below groups. If the outbreak occurred in only a single or limited number of sections of the major setting of exposure (i.e. exposure did not occur throughout the entire setting of exposure), only include the total number of residents or staff in that section or sections. For example, an outbreak restricted to single ward of a hospital should include only patients and staff assigned to that ward as exposed.

- **Residents, guests, passengers, patients, etc.** – Persons who do not work in the major setting, such as children attending daycare, residents of a nursing home, guests of a hotel, prison inmates, students at a school, etc. If exposure occurs in a work place such as an office building, consider all persons exposed and/or ill as residents/guests.
- **Staff, crew, etc.** – Persons who work in the major setting, such as healthcare providers, teachers, camp counselors, prison guards, daycare employees, hotel staff, waiters, etc.

Other settings of exposure (Select all that apply)

If the person-to-person outbreak occurred in more than one setting of exposure, indicate all additional settings where exposure occurred. Refer to “Major setting of exposure” for setting descriptions. If the other setting of exposure is not listed, you may enter an additional setting of exposure by clicking the “Other...” text and entering in the desired setting of exposure. Check the provided list carefully to ensure that your setting of interest has not already been entered before entering a new setting of exposure.

Animals and Their Environment (Animal Tab)

Only complete this section if 'Animal Contact' was identified as the primary mode of transmission.

- **Setting of exposure** – Indicate the place or setting where cases were exposed. Choose from the settings provided, which includes private home, petting zoo, fair, etc.
- **Type of animal** – Indicate type of animal exposure the outbreak was related to the source of transmission. Choose from the list of animals provided, which includes both juvenile and adult animals, such as lamb and sheep, baby chick and chicken.
- **Remarks** – Briefly describe important aspects of the animal exposure not covered above.

Food-Specific Data (Food Tab)

Only complete this section if 'Food' was identified as the primary mode of transmission.

Food vehicle undetermined

Indicate if a food vehicle was *not* identified for the outbreak. If you check this box do not enter any food-related information.

Food Questions

Name of food

Excluding any method of preparation, indicate a single implicated food in Column 1. If there was more than one implicated food, enter the other implicated foods in Columns 2 and 3. Do not enter brand names in the food field. If you would like to report the brand of food, enter it into the Remarks field. For additional information on how to search for a food item or enter new foods, see the training guides for the Food tab. There are several ways to enter foods, ingredients, and contaminated ingredients associated with an outbreak. Examples are below.

Ingredient(s)

For the implicated food suspected or investigated, indicate all known ingredients in Column 1 for the implicated food reported in Column 1.

- If the contaminated ingredient(s) were identified, indicate so in the 'Contaminated ingredient' field.
- Select 'N/A' in the Selected Ingredients field if a single food vehicle is identified as the source of contamination (e.g. hazelnuts, raw milk).
 - A single food is defined as a food with all ingredients that can be categorized into only one of the 17 simple food commodities. For more information on commoditization of foods, visit: [Recipes for Foodborne Outbreaks: A Scheme for Categorizing and Grouping Implicated Foods](#).
- 'N/A' should be checked only in the Selected Ingredients field and not in the Contaminated Ingredient field.
- Select 'Unknown' as an ingredient when the ingredients of the food vehicle are unknown or could not be identified.
- If the ingredients of the food vehicle are known, but a single ingredient cannot be determined as the sole source of contamination, select the known ingredients and 'Unknown' from the ingredient pick list.

Contaminated ingredients

Among the ingredients previously listed in the Ingredient field (as it corresponds to the 'Name of Food'), indicate the contaminated ingredient(s) in the appropriate column. Multiple contaminated ingredients

can be entered for the corresponding implicated food and ingredient fields. Epidemiologic information can be used to determine contaminated ingredients.

Example 1: The implicated food for an outbreak was coleslaw, and contaminated source ingredient was cabbage. In Column 1, enter 'coleslaw' as 'Name of Food', and 'cabbage', 'mayonnaise', 'carrots', and 'raisins' as 'Ingredient(s)' and 'cabbage' as 'Contaminated Ingredient'.

Example 2: The implicated food for an outbreak was beef lasagna, and ground beef was identified as the contaminated source. In Column 1, report 'lasagna, beef' as 'Name of Food', and 'ground beef,' 'pasta,' 'mozzarella cheese, pasteurized,' and 'tomato sauce, unspecified' as 'Ingredient(s)' then list 'ground beef' as the 'Contaminated ingredient'.

Example 3: Cases consumed vegetarian pizza and French fries, but the contaminated source ingredient was roma tomato (via pizza). In Column 1, enter 'pizza, vegetable' as 'Name of Food' and 'tomatoes, roma,' 'zucchini,' 'mozzarella cheese, pasteurized,' and 'bread, unspecified' as the 'Ingredient(s)' and list 'Contaminated ingredient' as 'tomatoes, roma'. Because French fries were not identified as the source of contamination, French fries can be omitted from the report.

Example 4: The implicated foods for an outbreak were potato salad and fruit salad, and the source of contamination was not identified. In Column 1, report 'potato salad' as 'Name of Food' and if the ingredients are known, list them in the 'Ingredient(s)' fields and the 'Contaminated ingredient' field will be left blank. In Column 2, report 'fruit salad' for 'Name of Food,' list any known 'Ingredient(s),' and leave the 'Contaminated ingredient' field blank.

Number of cases exposed to implicated food

Enter the number of primary ill cases exposed to the implicated food.

Reason(s) suspected

For the implicated food, indicate the reason suspected. Choose the reason suspected from the list below; multiple selections are permitted. This variable is required for each implicated food reported.

- 1** – Statistical evidence from epidemiological investigation
- 2** – Laboratory evidence (e.g., confirmation of agent in food). Confirmation criteria available at http://www.cdc.gov/outbreaknet/references_resources/guide_confirming_diagnosis.html
- 3** – Compelling supportive information (e.g., improper food handling or food preparation, consumption of recalled food item, epidemiologic data that suggests a particular food, but the sample size of an outbreak does not allow for statistical significance).
- 4** – Other data (e.g., same phage type found on farm that supplied eggs; same PFGE pattern identified in a known foodborne disease outbreak)
- 5** – Specific evidence lacking but prior experience makes it likely source. For example, if affected persons in an outbreak are uncooperative during the investigation and refuse to be interviewed, so the epidemiologic data is missing. However, the etiology is *Salmonella* Enteritidis and the outbreak occurred at a brunch where the guests ate scrambled eggs. Prior experience indicates that the outbreak is likely related to foodborne contact with eggs.

Method of processing (Prior to point-of-service)

For the **lowest level of food** responsible for the outbreak (either contaminated ingredient or single ingredient implicated food), indicate the method of processing. The method of processing intends to capture any modifications to the contaminated source food before it arrives at the final point of use location. Choose the method of processing from the list; multiple selections are permitted. However, if multiple selections must be entered, enter one per contaminated ingredient by listing additional method of processing and contaminated ingredients in separate columns. If the lowest level of contamination is unknown, leave this field blank. Examples are below.

1 – Pasteurized: A food preservation process whereby fluid milk and others foods are heat-treated for a specified time and temperature to destroy all disease causing microorganisms and to reduce the total number of bacteria. These products should be labeled as having been pasteurized (e.g., fluid milk and milk products, juice, pasteurized egg-product, in-shell pasteurized eggs, etc.).

2 – Unpasteurized: Product that commonly is pasteurized for safety that has not gone through the pasteurization process. The product is not labeled as having been pasteurized (e.g., fluid milk, cheese, juice, etc.).

3 – Shredded or diced: Product that has been manually or mechanically shredded or diced at a processor and is received at the point of use without the need for further preparation except possible washing prior to service. This can also include shredded or diced cheese or meat that arrives at the point of service already shredded or diced.

4 – Pre-packaged: Packaged at the processor level and received at the point of use in a sealed bag or container (e.g., bagged lettuce or other produce).

5 – Irradiation: A controlled exposure of food to gamma rays from a radioactive source or to ionizing radiation to accomplish the equivalent of pasteurization. It may be labeled with a “radura” symbol or otherwise labeled to indicate that it was irradiated.

6 – Pre-washed: The pre-washed food product when received at the point of use is considered a washed product (majority will be labeled as ‘pre-washed’) and may or may not specify on its label whether subsequent washing prior to use is necessary.

7 – Frozen: Process of freezing food to temperatures zero degrees Fahrenheit or below for the preservation of food and/or to provide protection against foodborne pathogens such as parasites. The product arrives at the final point of use location already frozen. For example, if the product arrived at the restaurant fresh then the restaurant later froze the product, the ‘method of processing’ would not be ‘frozen.’

8 – Canned: The product arrived at the point of use in a can. Indicate ‘home-canned’ or ‘commercially-canned’ in the General Section: Remarks

9 – Acid treatment: The product arrived at the point of use having been made with an acid ingredient that would lower the pH for preservation and/or pathogen control. (e.g., commercial potato salad with vinegar)

10 – Pressure treated: The product arrived at the point of use labeled it had been pressure treated. This process destroys bacterial pathogens of concern. (e.g., oysters, juice, etc.)

11 – None or Unknown: Method of processing was not identified above or method of processing is unknown. Provide additional information in the General/Remarks

Example 1: The implicated food for an outbreak was chef salad, and contaminated ingredient was Swiss cheese (pasteurized). In Column 1, report ‘chef salad’ as ‘Name of Food’, enter ‘Swiss cheese, pasteurized’ in ‘Ingredient(s)’ and ‘Contaminated ingredient’ fields, and enter ‘1 – pasteurized’ as method of processing.

Example 2: The implicated food suspected for an outbreak was potato salad, and the contaminated ingredient was unknown. In Column 1, report 'potato salad' as 'Name of Food', provide any known ingredients in 'Ingredient(s)' fields, leave the 'Contaminated ingredient' fields blank, and do not select a method of processing for the suspected potato salad.

Example 3: Cases became ill after consuming chicken quesadilla in a fast food restaurant, and the contaminated ingredients were identified as both the pre-diced chicken and unpasteurized mozzarella cheese. In Column 1, report 'quesadilla, chicken' as 'Name of Food', enter 'chicken' in 'Ingredient(s)' and 'Contaminated ingredient' fields, and enter the appropriate method of processing for the chicken, in this case, '3 – Shredded or diced'. Then in Column 2, report 'quesadilla, chicken' as 'Name of Food', enter 'mozzarella, unpasteurized' in 'Ingredient(s)' and 'Contaminated ingredient' fields, then enter appropriate method of processing for the cheese, in this case, '2 – Unpasteurized'.

Method of preparation (At point-of-service: Retail: restaurant, grocery store)¹

For the **implicated food**, indicate the method of preparation. The method of preparation intends to capture any modifications to the implicated food after it arrives at the final point of use location, which will often be a retail establishment such as a restaurant or grocery store. In other words, how was the implicated food handled before it was served? Choose only one method of preparation from the list below; multiple selections are NOT permitted. Note that the provided examples are to be used as guides; allow the possibility that different establishments may practice different methods of preparation for the same food.

- 1 – Prepared in the home:** Food that is prepared in a private home and not in a regulated retail food establishment, such as a restaurant or grocery store that is regulated by a food regulatory authority. For example, game that was slaughtered, skinned, and/or butchered in a private home.
- 2 – Ready to eat food – No manual preparation, No cook step:** Food preparation with no cook step wherein ready-to-eat food is received, stored, held and served. For example, manufacturer pre-sliced cheese, pre-packaged deli meats, whole raw fruits, pre-shucked raw oysters.
- 3 – Ready to eat food – Manual preparation, No cook step:** Food preparation with no cook step wherein ready-to-eat food is received, stored, prepared, held and served. For example, cut fresh fruits and vegetables, chicken salad made on-site from canned chicken.
- 4 – Cook and Serve Foods – Immediate service:** Food preparation for same day service that involves a kill-step (cooked) wherein food is received, stored, prepared, cooked, and served. For example, food that is cooked to order and served immediately after preparation, such as soft-cooked eggs and hamburgers.
- 5 – Cook and hot hold prior to service:** Food preparation for same day service wherein food is received, stored, prepared, cooked, held and served. For example, hot dogs, fried chicken, soups, hot vegetables, and mashed potatoes.
- 6 – Advance preparation – Cook, cool, serve:** Complex food preparation wherein food is received, stored, prepared, cooked, and cooled during an extended period of time (several hours or a day or more) prior to service. For example, sliced roast beef from a whole cooked roast.
- 7 – Advance preparation – Cook, cool, reheat, serve:** Complex food preparation wherein food is received, stored, prepared, cooked, and cooled several hours or a day or more in advance of

service, then reheated immediately prior to service. For example: lasagna, casseroles, soups, gravies, sauces, and chili.

8 – Advance preparation – Cook, cool, reheat, hot hold, serve: Complex food preparation wherein food is received, stored, prepared, cooked, and cooled several hours or a day or more in advance of service, then reheated and held hot prior to service. For example: chili and refried beans.

9 – Advance preparation – Cook-chill and Reduced Oxygen Packaging (ROP): Complex food preparation wherein food is processed on-site in a retail food establishment so that it goes through a packaging procedure that results in a reduced level of oxygen in a sealed package. For example, sauces, gravies; cheeses packaged under ROP. ROP is an inclusive term and can include other packaging processes such as cook-chill and sous-vide. Cook-chill is a process that uses a plastic bag filled with hot cooked food from which air is expelled and which is closed with a plastic or metal crimp. Sous-vide is a specialized process of ROP for partially cooked ingredients alone or combined with raw foods that require refrigeration or frozen storage until the package is thoroughly heated immediately before service.

10 – None/Unknown: - Method of preparation is not identified above or method of preparation is unknown. Provide additional information in the General/Remarks

¹Descriptions adapted from the FDA document entitled, *Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments*, April 2006.

Level of preparation

For the **implicated food**, indicate level of preparation. Select one level of preparation from the list in the appendix. If the implicated food had multiple levels of preparation, reenter the food name and select the other level of preparation.

- 1** – Foods eaten raw with minimal or no processing. (e.g., washing, cooling).
- 2** – Foods eaten raw with some processing. (e.g., no cooking, fresh cut and/or packaged raw).
- 3** – Foods eaten heat processed (e.g., cooked: a microbiological kill step was involved in processing).

Contaminated food imported to US?

Indicate if the contaminated food was imported into the US. If the contaminated food was imported, indicate the name of the country, if known. Select No if the contaminated food was not imported into the US.

Was product both produced under domestic regulatory oversight and sold?

Indicate if the food product was produced under domestic regulatory oversight and sold under domestic regulatory oversight. Domestic regulatory oversight includes commercial products that are regulated by the FDA or locally produced food products for distribution regulated by local and state health authorities. Indicate Yes, if the food product was produced and sold under domestic regulatory oversight. For example, a loaf of bread produced and sold by a licensed local bakery, commercially canned foods, etc. Indicate No, if the food product was not produced under domestic regulatory oversight and/or not sold under domestic regulatory oversight; for example, homemade cheese (produced in personal home – no local/state oversight) sold in grocery stores or food establishments (this practice is illegal). Indicate Unknown, if whether the food product was produced under domestic

regulatory oversight is unknown or whether the food product was sold under domestic regulatory oversight is unknown.

Location where food was prepared (check all that apply)

Indicate the location where the implicated food(s) were prepared. Multiple selections are allowed. If there was a specific food item confirmed as the contaminated source, indicate only the location where that food item was prepared. Briefly describe important aspects of the location where the food was prepared in the 'Prepared/Remarks' below. The examples provided should be used as guides; it is nearly impossible to provide examples that would be applicable for every outbreak scenario. With that in mind, use your best judgment when indicating the 'location where food was prepared' and feel free to contact your NORS-Foodborne Regional Manager if additional guidance is needed.

- **Restaurant: 'Fast-food' (drive up service or pay at counter)** – Indicate if food was prepared at a fast food restaurant. We understand that this is a broad category, but consider fast-food restaurants any restaurant where patrons are not served by a server at a table and patrons are responsible for their own food tray, such as at McDonald's, Subway, etc.
- **Restaurant: Sit-down dining** – Indicate if food was prepared at a sit down dining restaurant. We understand that this is a broad category, but consider a sit-down dining restaurant any restaurant where restaurant staff directs patrons to their seat and the restaurant staff is responsible for clearing the tables, such as at buffet restaurants, Red Lobster, Chili's, etc. Many traditional sit-down restaurants now offer patrons an opportunity to have their food prepared to-go, identify such 'location where food was prepared' as a sit-down dining restaurant.
- **Restaurant: Other or unknown type** – Indicate if food was prepared at a restaurant, but the type of restaurant was not a 'fast-food' or sit-down dining restaurant or if unknown. It would be difficult to classify all restaurants; the examples above should be used as a guide. If you encounter a restaurant that does not fit into either 'fast-food' or 'sit-down' categorizations (a possible hybrid of the two), select this option and provide additional details in the Prepared/Remarks section below. For example, mall food court or stand-alone deli (based on establishment).
- **Private home** – Indicate if food was prepared at a private home.
- **Banquet Facility (food prepared and served on-site)** – Indicate if food was prepared and served on site. A banquet facility is typically a building/section of a building, equipped with an on-site kitchen/cooking facility, capable of serving individuals at an on-site dining area. For example, if a group of patrons dine in a sit-down restaurant's banquet room, indicate 'location where food was prepared' as 'restaurant: sit-down dining' and 'location where food was eaten' as 'banquet facility.'
- **Caterer (food prepared off-site from where served)** – Indicate if food was prepared off-site at a different location from where it was eaten. Event caterers typically prepare food off-site and deliver/set-up prepared food at another location.
- **Fair, festival, other temp or mobile services** – Indicate if food was prepared at a fair, festival or other temporary or mobile food service
- **Grocery store** – Indicate if food was prepared at grocery store, for example deli department or seafood department of a grocery store.
- **Workplace, not cafeteria** – Indicate if food was prepared at a workplace, but **not** at a work cafeteria. For example, a worker uses the workplace kitchenette (stove, toaster, etc.) to prepare lunch.

- **Workplace cafeteria** – Indicate if food was prepared at a workplace cafeteria. Typically, the workplace cafeteria will be a separate cooking facility where cafeteria staff will prepare and serve food; the cafeteria should contain a dining area.
- **Nursing home, assisted living facility, home care** – Indicate if food was prepared at a nursing home, assisted living facility, or home care
- **Hospital** – Indicate if food was prepared at a hospital
- **Child day care center** – Indicate if food was prepared at a child day care center
- **School** – Indicate if food was prepared at a school (kindergarten through college)
- **Prison, jail** – Indicate if food was prepared at a jail or prison
- **Church, temple, religious location** – Indicate if food was prepared at a church, temple or other religious location
- **Camp** – Indicate if food was prepared at a camp. A camp may include any designated place used for overnight stay outdoors, including but not limited to summer camps for youth with formal kitchen, a day camp that serves food, a commercial firm that hosts trips such as rafting or horseback riding, family vacations where a fire pit or small burners are used to prepare food, etc.
- **Picnic** – Indicate if food was prepared at a picnic. A picnic is typically a meal prepared outdoors with no overnight stay, such as food prepared during a company picnic/cookout or a couple prepares small sandwiches outdoors.
- **Other (describe in Prepared/Remarks)** – If food was prepared at a location that cannot be described from the above choices, indicate 'Other' and explain in the Remarks below.
- **Unknown** – If information on location where food was prepared is not known, indicate unknown
- **Remarks** – Indicate any other information related to the location where prepared, and if 'Other' location where food prepared was indicated, describe here.

Location of exposure (where food was eaten) (check all that apply)

Indicate the location where the implicated food(s) were eaten. Multiple selections are allowed. Briefly describe important aspects of the location of exposure in the Eaten/Remarks below. The examples provided should be used as a guide; it would be nearly impossible to provide examples that would be applicable for every outbreak scenario. With that in mind, use your best judgment when indicating the 'where food was eaten' and feel free to contact your NORS-Foodborne Regional Manager if additional guidance is needed.

- **Restaurant: 'Fast-food' (drive up service or pay at counter)** – Indicate if food was eaten at a fast food restaurant. We understand that this is a broad category, but consider fast-food restaurants any restaurant where the customers are not served by a server at a table and the customers are responsible for clearing their own food tray, such as McDonald's, Subway, etc.
- **Restaurant: Sit-down dining** – Indicate if food was eaten at a sit down dining restaurant. We understand that this is a broad category, but consider a sit-down dining restaurant any restaurant where restaurant staff directs patrons to their seat and the staff is responsible for clearing the tables, such as at buffet restaurants, Red Lobster, Chili's, etc. Many traditional sit-down restaurants now offer patrons an opportunity to have their food prepared to-go so the patron may eat his/her food outside of the restaurant; in that case, indicate the appropriate location 'where food was eaten,' but it should not be 'restaurant: sit-down dining.'
- **Restaurant: Other or unknown type** – Indicate if food was eaten at a restaurant, but the type of restaurant was not a 'fast-food' or sit-down dining restaurant or if unknown. It would be difficult to classify all restaurants; the examples above should be used as a guide. If you encounter a restaurant that does not fit into either 'fast-food' or 'sit-down' categorizations (a possible hybrid of

the two), select this option and provide additional details in the Eaten/Remarks section below. For example, mall food court or deli (based on establishment).

- **Private home** – Indicate if food was eaten at a private home.
- **Banquet Facility (food prepared and served on-site)** – Indicate if food was eaten at a location where food is prepared and served on site. A banquet facility is typically a building/section of a building, equipped with an on-site kitchen/cooking facility, capable of serving individuals at an on-site dining area. For example, a group of people dines in a restaurant’s banquet room, indicate ‘location where food was eaten’ as ‘banquet facility’ and indicate ‘location where food was prepared’ as ‘restaurant: sit-down dining.’
- **Caterer (food prepared off-site from where served)** – Indicate if food was eaten at caterer’s business establishment. This may not be a common exposure in an outbreak, but indicate ‘where food eaten’ as ‘caterer’ if the food was actually eaten at a caterer’s business establishment, such as at a food sampling event.
- **Fair, festival, other temp or mobile services** – Indicate if food was eaten at a fair, festival or other temporary or mobile food service
- **Grocery store** – Indicate if food was eaten at grocery store.
- **Workplace, not cafeteria** – Indicate if food was eaten at a workplace, but **not** at a work cafeteria. For example, a worker may eat lunch at his or her desk.
- **Workplace cafeteria** – Indicate if food was eaten at a workplace cafeteria. Typically, the workplace cafeteria will be a separate cooking facility where cafeteria staff will prepare and serve food; the cafeteria should contain some sort of dining area.
- **Nursing home, assisted living facility, home care** – Indicate if food was eaten at a nursing home, assisted living facility, or home care
- **Hospital** – Indicate if food was eaten at a hospital
- **Child day care center** – Indicate if food was eaten at a child day care center
- **School** – Indicate if food was eaten at a school (kindergarten through college)
- **Prison, jail** – Indicate if food was eaten at a jail or prison
- **Church, temple, religious location** – Indicate if food was eaten at a church, temple or other religious location
- **Camp** – Indicate if food was eaten at a camp. A camp may include any designated place used for overnight stay outdoors, including but not limited to summer camps for youth, a day camp that serves food or a commercial firm that hosts trips such as rafting or horseback riding, outdoor family vacations, etc.
- **Picnic** – Indicate if food was eaten at a picnic. A picnic is typically a meal prepared and eaten outdoors with no overnight stay, such as food eaten at a company picnic/cookout.
- **Other (describe in Eaten/Remarks)** – If food was eaten at a location that cannot be described from the above choices, indicate ‘Other’ and explain in the Remarks below.
- **Unknown** – If information on location where food was eaten is not known, indicate unknown
- **Remarks** – Indicate any other information related to the location where eaten, and if ‘Other’ location where food eaten was indicated, describe here.

Contributing Factors

For guidance on contamination, proliferation/amplification, and survival factors, see guidance diagram and text on page 41.

The confirmed or suspected point of contamination (check only one)

Indicate if the confirmed or suspected point of contamination occurred 'Before preparation' or at 'Preparation.' For example, if a multistate outbreak was linked by PFGE to samples obtained from a processing plant, one might conclude that the contamination occurred 'before preparation.' Often, it will be difficult to make this delineation without a traceback investigation, but indicate based on your investigation whether you would conclude that contamination occurred before preparation or at preparation.

- If the confirmed or suspected point of contamination occurred '**before preparation**,' indicate if it occurred at 'Pre-Harvest,' 'Processing,' or 'Unknown.' Further evidence might permit determining whether the point of contamination occurred at 'pre-harvest' (FDA traceback to farm fields) or 'processing' (FDA traceback to leaking roof at plant).

Reason suspected (check all that apply)

Indicate the reason why the confirmed or suspected point of contamination was assumed. Such examples include environmental evidence, (e.g., soil sample collected contaminated lettuce field), epidemiologic evidence (e.g., implicated food identified through a case-control study), laboratory evidence (e.g., laboratory confirmation obtained from food specimen or patient specimen), or that prior experience makes this a likely source of contamination.

Was food worker implicated as the source of contamination?

Indicate if food worker was implicated. A foodworker only refers to someone close to the point of service for the contaminated food. Any information regarding food pickers working in fields or sorters working in packaging plants should be placed in the traceback comments field.

- If **Yes**, indicate the type of evidence that implicated the food worker, laboratory and/or epidemiologic evidence, or that prior experience makes this a likely source of contamination. Place any additional information in the Remarks field on the Gen-Pt3 tab.

School Questions

Complete this section only if school is checked in either sections "Location where food was prepared" or "Location of exposure (where food eaten)". Complete this section even if the outbreak did not involve students or the school lunch program.

1. Did the outbreak involve a single or multiple schools?

Indicate if a single or multiple schools were involved in the outbreak. If multiple schools were involved in the outbreak, enter the number of schools.

2. School characteristics (for all involved students in all involved schools):

a. Total approximate enrollment

Indicate the approximate number of students enrolled in the school. Indicate if the number of students is unknown.

b. Grade level(s)

Indicate the grade level of the students in the outbreak; if more than one grade level applies, indicate all grade levels that apply.

- **Preschool** – An educational institution for children too young to attend elementary school
- **Grade school (grades K-12)** – Formal school for children from kindergarten to grade 12. Indicate all grades affected.
- **College/university/technical school** – Formal educational institution for students after high school
- **Unknown or Undetermined** – Indicate unknown or undetermined, if the grade level of the involved students are unknown or could not be determined

c. Primary funding of involved schools

- **Public** – All tuition is funded through the state or county
- **Private** – Parents of students cover all tuition.
- **Unknown** – Funding for school is unknown

3. Describe the preparation of the implicated item: (check all that apply)

Indicate how the implicated food item was prepared.

- **Heat and serve (item mostly prepared or cooked off-site, reheated on-site)** – Food has been prepared and cooked offsite but is heated and served on site
- **Served a-la-carte** – The food was not part of a USDA reimbursable meal
- **Serve only (preheated or served cold)** – Food is received hot at the school, held hot and served hot or received cold at the school, held cold and served cold
- **Cooked on site using primary ingredients** – Food is cooked on site
- **Provided by a food service management company** – Food is provided by a food service company
- **Provided by a fast-food vendor** – Food provided by a fast-food vendor
- **Provided by a pre-plate company** – Food that is already prepared and plated and usually just requires heating
- **Part of a club or fundraising event** – Food that is served at a club or fundraiser event
- **Made in the classroom** – Food that is prepared in a classroom
- **Brought by a student/teacher/parent** – Food that is brought into school by a student, teacher or parent
- **Other (describe in General/Remarks)** – If implicated item was prepared by a method that cannot be described from the above choices, indicate 'Other' and describe in General Section/Remarks.
- **Unknown or Undetermined** – Indicate if the preparation of the implicated item is unknown or cannot be determined

4. How many times has the state, county or local health department inspected this school cafeteria or kitchen in the 12 months before the outbreak?

Indicate how many times the school cafeteria or kitchen has been inspected in the last 12 months by state, county, or local health departments. If the school cafeteria or kitchen was not inspected, indicate 'Not inspected' or if the inspection status was unknown or undetermined. If multiple schools are involved, answer according to the most affected school.

5. Does the school have a HACCP (Hazard Analysis and Critical Control Point) plan in place for the school feeding program?

Indicate whether the school involved in the outbreak has a HACCP plan in place for the school feeding program. If multiple schools are involved, answer according to the most affected school.

6. Was implicated food item provided to the school through the National School Lunch/Breakfast Program?

Indicate whether the implicated item was served as part of the National School Lunch/Breakfast Program, and used commodities purchased and distributed by USDA for use in schools

- **If Yes, was the implicated food item donated/purchased by:**

If the school participates in the National School Lunch/Breakfast Program, indicate the source of the implicated food items: 'USDA through the Commodity Distribution Program,' 'The state/school authority,' 'Other (provide name in General Section/Remarks),' or 'Unknown or Undetermined'. Multiple selections are not permitted.

Ground Beef

Complete this section only if 'ground beef' was indicated as the food vehicle and/or contaminated ingredient.

1. What percentage of ill persons (for whom information is available) ate ground beef raw or undercooked (any visible pink)?

Enter the percentage of ill persons who ate raw or undercooked ground beef. Base the percentage reported on whom information is available.

2. Was ground beef case-ready?

Indicate whether the ground beef was case ready. Case-ready ground beef is meat that comes from a manufacturer packaged for sale that is not altered or repackaged by the retailer.

3. Was the beef ground or reground by the retailer?

Indicate if the beef was ground or reground by the retailer. That is, the retailer altered the beef from the manufacturer by grinding or regrinding.

- **If Yes, was anything added to the beef during grinding?** Indicate if anything, such as shop trim or any product to alter the fat content was added to the beef during grinding.

Additional Salmonella Questions

Complete this section for Salmonella outbreaks only.

- 1. Phage type(s) of patient isolates** – Enter the phage types of patient isolates, and if RDNC (Reacts, Does Not Conform), include the number. Do not enter PFGE patterns in this field.

Eggs

Complete this section only if 'egg' was indicated as the food vehicle and/or contaminated ingredient.

1. Were eggs: (Check all that apply)

Indicate if the eggs were 'in shell, unpasteurized,' 'in shell, pasteurized,' 'packaged liquid or dry,' 'stored with inadequate refrigeration during or after sale,' 'consumed raw,' 'consumed undercooked,' or 'pooled'

Guidance document for reporting all waterborne (General reporting sections only) and enteric foodborne, person-to-person, environmental, animal contact, and unknown/indeterminate mode of transmission outbreaks

2. Was Salmonella Enteritidis found on the farm?

Indicate if *Salmonella* Enteritidis was identified at the farm where the eggs originated.

Comment

Provide any additional information related to eggs and this outbreak, such as eggs and patients' isolates matched by phage type.

Appendix A

It may be difficult to determine whether some outbreaks should be reported as foodborne or waterborne. Use the following table to help you decide which type of report to enter.

Source of Outbreak (Known or Suspected)	If...	Select Primary Mode of Transmission:
FOOD	Contaminated food goes in your mouth and makes you sick	Foodborne
	Food is produced or prepared using contaminated water and then the contaminated food is consumed	Foodborne
WATER	Contaminated water goes in your mouth, you breathe it, or you contact it in another way and it makes you sick	Waterborne
ICE	Ice is made with contaminated water	Waterborne
	Ice is made with contaminated water and then added to a beverage (e.g., ice was made with contaminated water and only people who consume drinks containing ice became ill)	Waterborne
	Ice is made with contaminated water and is used to cool an implicated food product	Foodborne
	Ice is already made and then becomes contaminated through handling	Foodborne
	Unknown how the ice became contaminated	Foodborne
BEVERAGES PREPARED WITH WATER	Beverage is made with contaminated water	Waterborne
	Beverage is already made and then becomes contaminated through handling	Foodborne
	Flavoring (e.g., frozen orange juice concentrate) is contaminated	Foodborne
	Unknown how the beverage became contaminated	Foodborne
DRINK MIX/SODA MACHINES	Water entering the 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)	Waterborne
	Drink is contaminated through handling after it is dispensed or contamination of the spout on the machine	Foodborne
	Flavoring is contaminated before it is put into the machine	Foodborne
	Unknown how the beverage became contaminated	Foodborne
BOTTLED WATER	Bottled water is contaminated anywhere in the chain from source water through production, storage, transportation, distribution, and point of use	Waterborne
FLAVORED DRINKS (note: flavoring does not include carbonation)	Flavoring is added to bottled water and then it becomes contaminated or if the flavoring is contaminated	Foodborne
	Water is contaminated before the flavoring is added	Waterborne
	Unknown how the flavored bottled water became contaminated	Foodborne

Appendix B

Information regarding Freedom of Information Act (FOIA) and data requests of NORS data

All outbreak information will be reviewed by the CDC FOIA office for identifiable information and considered for redaction by the CDC FOIA office. Our team provides guidance for which fields are most likely to require redaction, but we do not have final say in what is released.

For non-FOIA data requests, all remarks and comments will not be released due to possible identification of individual cases. Additionally, County, City/Town/Place of Exposure, and State Lab ID will not be released, as well as any sensitive or identifying information in attached documents. In order to protect the author or contact person of the outbreak report, the Reporting Agency will also not be released.

NORS Guidance for Contributing Factors (CF)

CONTRIBUTING FACTORS

Introduction

Contributing factors (CFs) are defined as the food safety practices and behaviors which most likely contributed to a foodborne illness outbreak. A CF should be identified only if the investigator has strong evidence that it actually occurred in this outbreak; just because a factor has been cited in similar outbreaks in the past does not mean it was involved in this outbreak.

Please select any and all CFs that are causally associated with the outbreak.

After consideration of all epidemiological, laboratory, and environmental assessment information available, if contributing factors for this outbreak could not be determined, then at the top of the contributing factors section, the box “Contributing Factors Unknown” should be checked. If this box is checked, then the remainder of the contributing factors section should be left completely blank.

Classification

CFs are classified into 3 categories (contamination, proliferation/amplification, and survival factors):

Contamination Factors

- Factors that introduce or otherwise permit contamination.
- Contamination factors relate to how the etiologic agent got onto or into the food vehicle.
- There are 15 contamination factors, numbered C1 – C15.
- C-N/A is utilized if contamination factors were not related to the type of etiologic agent involved in the outbreak. C-N/A should rarely, if ever, be cited.
- If no contamination factors were identified, then leave all contamination factors blank. Then, please explain why contamination factors could not be identified in the “Remarks” section at the end of this report.

Proliferation/Amplification Factors

- Factors that allow proliferation or growth of etiologic agents.
- Citation of proliferation/amplification factors is only applicable when bacterial agents are involved.
- Proliferation factors relate to how bacterial agents were able to increase in numbers and/or produce toxic products prior to the vehicle being ingested.
- There are 12 proliferation/amplification factors, numbered P1 – P12.

- P-N/A is utilized if proliferation/amplification factors are not related to the type of etiologic agent involved in the outbreak. For example, proliferation/amplification factors would not be cited in a viral outbreak.
- If no proliferation/amplification factors were identified, then leave all proliferation/amplification factors blank. Then, please explain why proliferation/amplification factors could not be identified in the “Remarks” section at the end of this report.

Survival Factors

- Factors that allow survival or fail to inactivate the contaminant.
- Citation of survival factors is only applicable when microbial agents are involved.
- Survival factors refer to processes or steps that should have eliminated or reduced the microbial agent but did not because of one of these factors.
- There are 5 survival factors, numbered S1 – S5.
- S-N/A is utilized if survival factors were not related to the type of etiologic agent involved in the outbreak. For example, survival factors would not be cited in a scombroid toxin outbreak.
- If no survival factors were identified, then leave all survival factors blank. Then, please explain why survival factors could not be identified in the “Remarks” section at the end of this report.

How to Identify Contributing Factors in an Outbreak

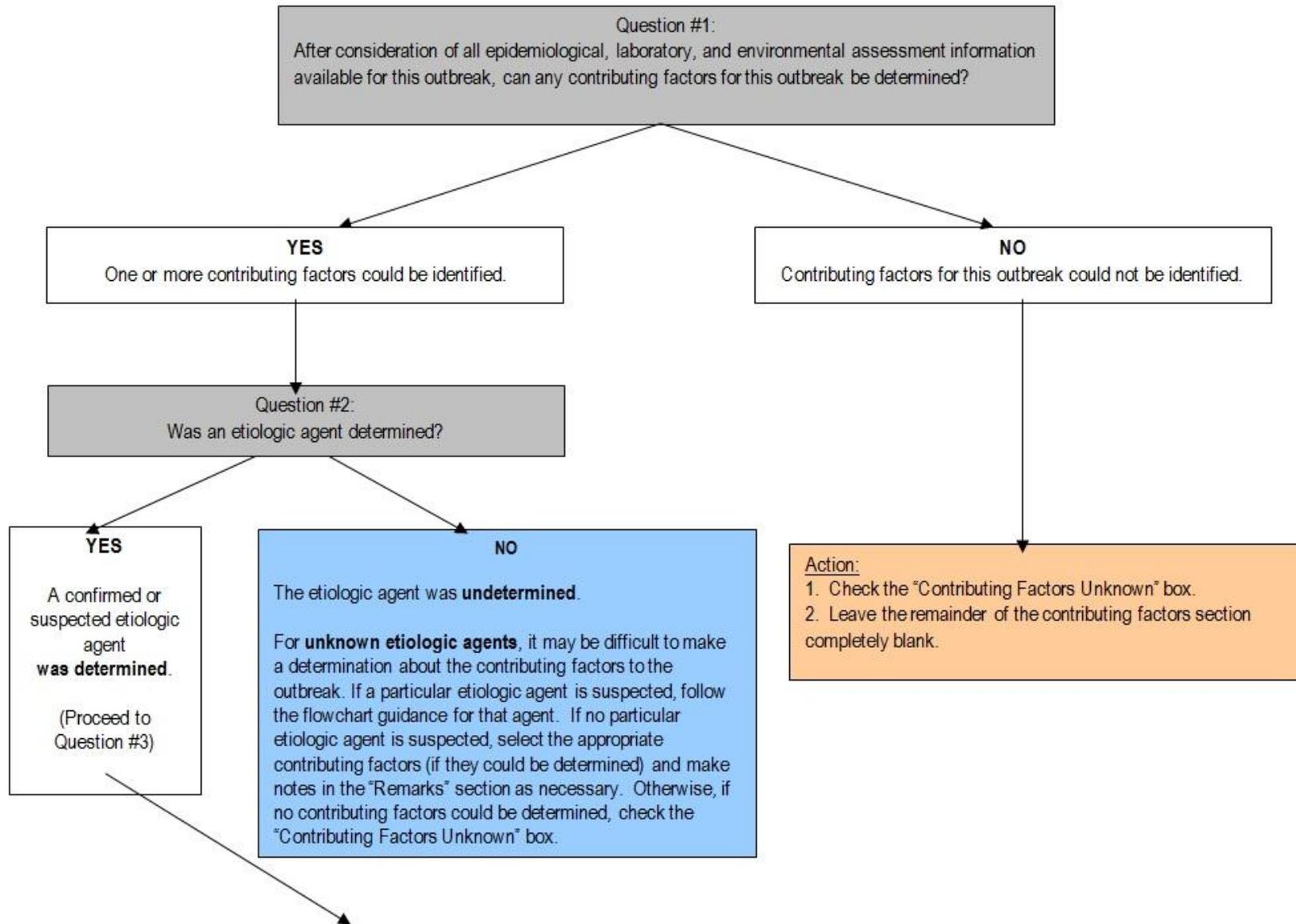
In a food borne outbreak, an environmental assessment is a systematic process designed to gather as much information as possible to describe the environmental circumstances prior to the exposure(s) that caused a foodborne outbreak. From this evaluation process, factors that most likely contributed to the outbreak may be identified. Each environmental assessment will be unique to a specific outbreak. It should include some or all of the following:

- a) A visit to the location where suspected food vehicles are grown, harvested, processed, prepared and/or served;
- b) A review of the physical facilities and the equipment used;
- c) Interviews with those involved in the harvest, processing, handling and/or preparation of the implicated foods;
- d) A review of the menus in food-service establishments such as restaurants, delis, quick service restaurants, or institutional food service facilities including schools, nursing homes, and hospitals;
- e) Development of a food flow for implicated foods that includes notes on preparation policies and practices, points of possible contamination and individuals involved, and/or;
- f) Reenactment of the preparation of foods involved in the outbreak.

Note:

- Identification of contributing factors should be based on an environmental assessment of the outbreak, *not results of routine environmental inspections*. For example, during an outbreak investigation, improper cooling may be observed. This risky practice may or may not be relevant to the outbreak. Contributing factors cited should fit within the context of epidemiological and laboratory findings for the outbreak wherever possible.
- Reporting of contributing factors should not be limited to outbreaks associated with food-service establishments such as restaurants. They can be reported when associated with other outbreak locations as well.

Contributing Factors Flowchart for Foodborne Disease Outbreaks



Question #3:
What type of etiologic agent (confirmed or suspected) was involved in the outbreak?

Bacterial

Viral or parasitic

Non-infectious or chemical etiologic agent

Question #4A: Were contamination factors applicable to the outbreak? (They almost always should be for bacterial pathogens.)

Question #4B: Were proliferation / amplification factors applicable to the outbreak? (They typically should be for bacterial pathogens.)

Question #4C: Were survival factors applicable to the outbreak?

Question #4A: Were contamination factors applicable to the outbreak? (They almost always should be for viral or parasitic pathogens.)

Question #4B - NONE: Proliferation / amplification factors are not applicable for viral or parasitic pathogens.

Question #4C: Were survival factors applicable to the outbreak?

Question #4A: Were contamination factors applicable to the outbreak? (They almost always should be for non-infectious/chemical agents.)

Question #4B - NONE: Proliferation / amplification factors are not applicable for non-infectious/chemical agents.

Question #4C - NONE: Survival factors are not applicable for non-infectious/chemical agents.

YES

NO
Action:
Select "C-N/A"

YES

NO
Action:
Select "P-N/A"

YES

NO
Action:
Select "S-N/A"

YES

NO
Action:
Select "C-N/A"

Action:
Select "P-N/A"

YES

NO
Action:
Select "S-N/A"

YES

NO
Action:
Select "C-N/A"

NO
Action:
Select "P-N/A"

NO
Action:
Select "S-N/A"

Question #5A: Could contamination factors be determined?

Question #5B: Could proliferation / amplification factors be determined?

Question #5C: Could survival factors be determined?

Question #5A: Could contamination factors be determined?

Question #5C: Could survival factors be determined?

Question #5A: Could contamination factors be determined?

YES
Action:
Select all relevant contamination factors: C1 - C15.

YES
Action:
Select all relevant proliferation / amplification factors: P1 - P12.

YES
Action:
Select all relevant survival factors: S1 - S5.

YES
Action:
Select all relevant contamination factors: C1 - C15.

YES
Action:
Select all relevant survival factors: S1 - S5.

YES
Action:
Select all relevant contamination factors: C1 - C15.

NO
Action:
1. Do NOT select any contamination factors.
2. Make a note in the "Remarks" section that contamination factors could not be determined by the investigation.

NO
Action:
1. Do NOT select any proliferation / amplification factors.
2. Make a note in the "Remarks" section that proliferation / amplification factors could not be determined by the investigation.

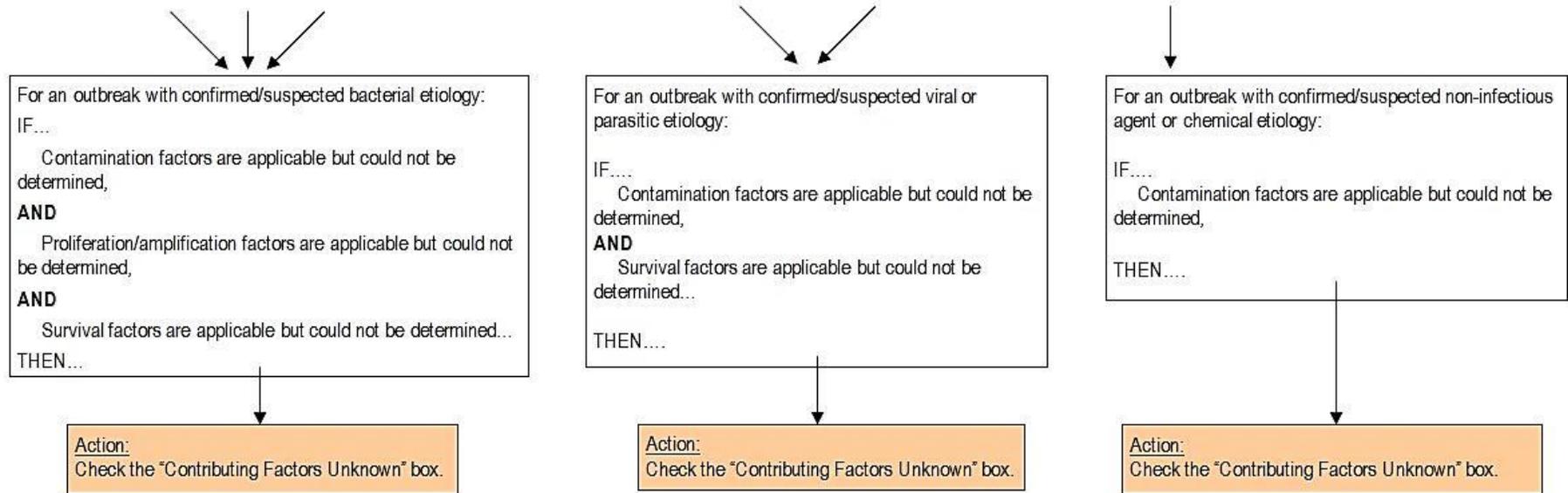
NO
Action:
1. Do NOT select any survival factors.
2. Make a note in the "Remarks" section that survival factors could not be determined by the investigation.

NO
Action:
1. Do NOT select any contamination factors.
2. Make a note in the "Remarks" section that contamination factors could not be determined by the investigation.

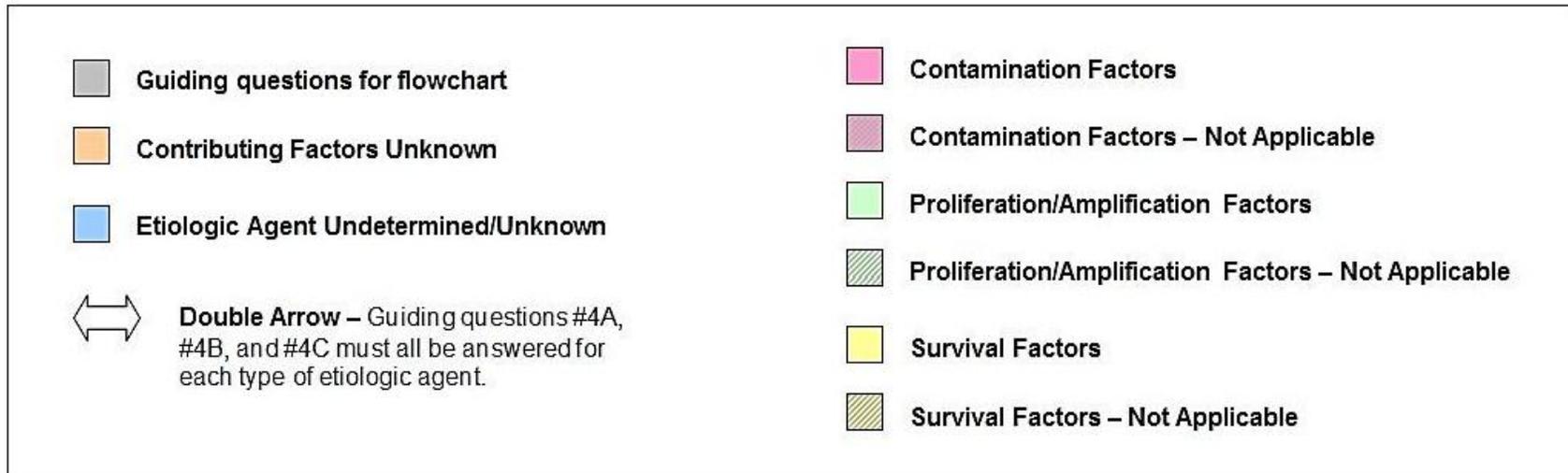
NO
Action:
1. Do NOT select any survival factors.
2. Make a note in the "Remarks" section that survival factors could not be determined by the investigation.

NO
Action:
1. Do NOT select any contamination factors.
2. Make a note in the "Remarks" section that contamination factors could not be determined by the investigation.

Guidance document for reporting all waterborne (General reporting sections only) and enteric foodborne, person-to-person, environmental, animal contact, and unknown/indeterminate mode of transmission outbreaks



Legend for Flowchart



Contributing Factors Unknown		
Code	Factor	Description
CF Unknown	Contributing Factors Unknown	<p>Title CF Unknown – Contributing Factors Unknown</p> <p>Definition/Explanation After consideration of all epidemiological, laboratory, and environmental assessment information available, if contributing factors for this outbreak could not be determined, then at the top of the contributing factors section, the box “Contributing Factors Unknown” should be checked. If this box is checked, then the remainder of the contributing factors section should be left completely blank.</p>

Contamination Factors		
Factors that introduce or otherwise permit contamination; contamination factors relate to how the etiologic agent got onto or into the food vehicle.		
Code	Factor	Description
C1	Toxic substance part of tissue	<p>Title C1 – Toxic substance part of the tissue</p> <p>Definition/Explanation A natural toxin found in a plant or animal, or in some parts of a plant, animal, or fungus; -OR- A chemical agent of biologic origin that occurs naturally in the vehicle or bioaccumulates in the vehicle prior to or soon after harvest.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Mushroom poisoning due to consumption of toxic mushrooms. • Ciguatera fish poisoning due to consumption of tropical marine finfish which have bio accumulated naturally-occurring ciguatera toxins through their diet. • Scombroid fish poisoning due to consumption of fish containing elevated levels of histamine should be cited as C1. However, if there is environmental or traceback evidence of temperature abuse, then please also identify P4 or P5 (as appropriate) in addition to C1. <p>Notable Exceptions None.</p>

Code	Factor	Description
C2	Poisonous substance intentionally / deliberately added	<p>Title C2 – Poisonous substance intentionally/deliberately added</p> <p>Definition/Explanation A poisonous substance intentionally/deliberately added to a food in quantities sufficient to cause serious illness. Poisons added because of sabotage, mischievous acts, and attempts to cause panic or to blackmail a company fall into this category.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Cyanide or phenolphthalein deliberately added to food to cause illness. • Methomyl pesticide intentionally added to food to cause illness. <p>Notable Exceptions None.</p>
C3	Poisonous substance accidentally / inadvertently added	<p>Title C3 – Poisonous substance accidentally/ inadvertently added</p> <p>Definition/Explanation A poisonous substance or chemical agent was accidentally/inadvertently added to the vehicle. This addition typically occurs at the time of preparation or packaging of the vehicle.</p> <p>Misreading labels, resulting in either mistaking poisonous substances for foods or incorporating them into food mixtures, would also fall into this category.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Sanitizer or cleaning compound accidentally added to food. <p>Notable Exceptions None.</p>

Code	Factor	Description
C4	Addition of excessive quantities of ingredients that are toxic in large amounts	<p>Title C4 – Addition of excessive quantities of ingredients that are toxic in large amounts</p> <p>Definition/Explanation An approved ingredient in a food can be accidentally added in excessive quantities so as to make the food unacceptable for consumption.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Niacin poisoning in bread. • Too great an amount of nitrites in cured meat. • Too great an amount of ginger powder in gingersnaps. <p>Notable Exceptions None.</p>
C5	Toxic container	<p>Title C5 – Toxic container</p> <p>Definition/Explanation 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 solution by contact with highly acid foods.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Galvanized containers with acid food • A toxic metal (e.g. zinc coated) container used to store highly acid foods <p>Notable Exceptions For this contributing factor, there may be confusion between foodborne outbreaks and waterborne outbreaks. If the outbreak is waterborne, then the contributing factors should be listed in the waterborne section, not in this foodborne section. In general, waterborne disease includes 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) – it's waterborne and should not be entered in the foodborne section. For ice, if ice is made with contaminated water – it's waterborne and should not be entered in the foodborne section. However, if ice is already made and then it becomes contaminated because it was stored in a toxic container – it's a foodborne outbreak and it would be appropriate to list C5 as a contributing factor.</p>

Code	Factor	Description
C6	Contaminated raw product – food was intended to be consumed after a kill step	<p>Title C6 – Contaminated raw product – food was intended to be consumed after a kill step</p> <p>Definition/Explanation The vehicle or a component of the vehicle contained the agent when it arrived at the point of final preparation or service. This contributing factor applies to foods intended to be consumed after undergoing a kill step (such as cooking to the required temperature) but this food processing step was insufficient to lower the levels of the pathogen below an infectious dose.</p> <p><i>Note:</i> Lab confirmation or a formal traceback can support or confirm the identification of this contributing factor (i.e. a traceback identifies a flock, herd, or farm as the source of the pathogen). If a lab results are available or if a traceback was conducted, please complete the lab confirmation and/or the traceback sections (as appropriate) in this outbreak’s NORS report.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • A hamburger was ordered well-done or medium-well, but it was subsequently undercooked. • When it arrived at final preparation, raw chicken was contaminated with <i>Salmonella</i>, which was then <u>un</u>intentionally undercooked. <p>Notable Exceptions None.</p>
Code	Factor	Description
C7	Contaminated raw product – food was intended to be consumed raw or undercooked / under-processed	<p>Title C7 – Contaminated raw product – food was intended to be consumed raw or undercooked/under-processed</p> <p>Definition/Explanation Contaminated products are ingested raw without being first subjected to a cooking step or another form of a kill step sufficient to kill any pathogens present. This contributing factor applies to foods intended to be consumed raw, as well as foods intended to be consumed after mild heating, or another process which does not ensure pathogen destruction.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • A hamburger or steak ordered to be prepared “rare” • Raw milk • Raw oysters or other shellfish • Raw produce • Unpasteurized cider or juices

		<ul style="list-style-type: none"> • Certain dishes where raw or rare beef is consumed • Foods that are intentionally not fully-cooked such as hollandaise sauce containing raw egg yolk or sunny-side-up eggs where the yolk was not denatured. • Ceviche (citrus-marinated seafood appetizer which is intentionally served without prior heating) • Prosciutto (aged, dry-cured, spiced Italian ham which is served uncooked) • Salted cod (dry-salted cod fish which is served uncooked) or cold-smoked salmon <p><u>Notable Exceptions</u> None.</p>
Code	Factor	Description
C8	Foods originating from sources shown to be contaminated or polluted (such as a growing field or harvest area)	<p><u>Title</u> C8 – Foods originating from sources shown to be contaminated or polluted (such as a growing field or harvest area)</p> <p><u>Definition/Explanation</u> Foods that originated from sources shown to be contaminated or polluted (such as a growing field or harvest area).</p> <p><i>Note:</i> Formal traceback may support or confirm the identification of this contributing factor. This factor would typically be cited along with another contamination factor, such as C6 or C7.</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • Shellfish from sewage-polluted waters or closed beds • Crops watered by contaminated irrigation water • Produce grown in contaminated soil <p><u>Notable Exceptions</u> None.</p>
Code	Factor	Description
C9	Cross-contamination of ingredients (cross-contamination does not include ill food workers)	<p><u>Title</u> C9 – Cross-contamination of ingredients (cross-contamination does not include ill food workers)</p> <p><u>Definition/Explanation</u> The pathogen was transferred to the vehicle by contact with contaminated worker hands, equipment, or utensils; drippage or spillage. If worker hands were the mode of contamination, the worker was not infected with or a carrier of the pathogen.</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • Contaminated raw poultry was prepared on a cutting board, and later, a ready-to-eat food was cross-

		<p>contaminated because it was prepared on this same cutting board without intervening cleaning.</p> <ul style="list-style-type: none"> • A worker’s hands became contaminated by raw foods, and subsequently, a ready-to-eat food was cross-contaminated because the worker’s hands touched this ready-to-eat food without intervening hand-washing. • Cloths, sponges, and other cleaning aids are used to clean equipment that processed contaminated raw foods. Before next use, these cleaning items were not disinfected; instead, these cleaning items are used to wipe surfaces that come in contact with foods that are not subsequently heated. • Contaminated raw foods touch or fluids from them drip onto foods that are not subsequently cooked. <p><u>Notable Exceptions</u> This contributing factor only applies to foods that are cross-contaminated by other ingredients. If food contamination was the direct result of the storage environment, then it should be cited in C14 (storage in contaminated environment).</p>
Code	Factor	Description
C10	<i>Bare-hand contact by a food handler / worker / preparer who is suspected to be infectious</i>	<p><u>Title</u> C10 – <i>Bare-hand</i> contact by a food handler/worker/preparer who is suspected to be infectious</p> <p><u>Definition/Explanation</u> A food worker, who is suspected to be infectious, uses his/her <i>bare</i> hands to touch/prepare foods that are not subsequently cooked.</p> <p>The term “infectious” is an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen.</p> <p>Potential reasons to suspect that a food worker is “infectious”: a) The food worker recently displays or admits a combination of foodborne disease symptoms (such as diarrhea, vomiting, nausea, fever, etc.) that may be similar to symptoms identified in those who are ill in the outbreak investigation; b) If a food worker’s household member exhibits similar symptoms directly preceding the outbreak; c) The food worker tested positive for a foodborne pathogen; d) Other epidemiologically- or environmentally-linked reasons.</p> <p><i>Note:</i> C10 should only be cited if there is evidence of bare-hand contact of an implicated food item. If there is no evidence of bare-hand contact or it is unknown whether the food worker was wearing gloves or not, then cite C12 instead. If there is evidence for both bare-hand contact and gloved-hand contact with the implicated food item, both C10 and C11 should be cited.</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins. <p><u>Notable Exceptions</u> None.</p>

Code	Factor	Description
C11	Glove-hand contact by a food handler / worker / preparer who is suspected to be infectious	<p>Title C11 – <i>Glove-hand</i> contact by a food handler/worker/preparer who is suspected to be infectious</p> <p>Definition/Explanation A food worker, who is suspected to be infectious, uses his/her <i>gloved</i>-hands to touch/prepare foods that are not subsequently cooked.</p> <p>The term “infectious” is an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen.</p> <p>Potential reasons to suspect that a food worker is “infectious”: a) The food worker recently displays or admits a combination of foodborne disease symptoms (such as diarrhea, vomiting, nausea, fever, etc.) that may be similar to symptoms identified in those who are ill in the outbreak investigation; b) If a food worker’s household member exhibits similar symptoms directly preceding the outbreak; c) The food worker tested positive for a foodborne pathogen; d) Other epidemiologically- or environmentally-linked reasons.</p> <p><i>Note:</i> C11 should only be cited if there is evidence of glove-hand contact of an implicated food item. If there is no evidence of glove-hand contact or it is unknown whether the food worker was wearing gloves or not, then cite C12 instead.</p> <p>If there is evidence for both bare-hand contact and gloved-hand contact with the implicated food item, both C10 and C11 should be cited.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins. <p>Notable Exceptions None.</p>
Code	Factor	Description
C12	Other mode of contamination (excluding cross-contamination) by a food handler / worker / preparer who is suspected to be infectious	<p>Title C12 – Other mode of contamination (excluding cross-contamination) by a food handler/worker/preparer who is suspected to be infectious</p> <p>Definition/Explanation A food worker, who is suspected to be infectious, contaminates the food by another mode of contamination other than bare-hand contact or glove-hand contact, or epidemiological/ environmental investigation determines that an infectious food worker contaminates food with his/her hands but the investigation is unable to determine whether or not the food worker was wearing gloves during food preparation. This contaminated food is subsequently not cooked.</p>

		<p>The term “infectious” is an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen.</p> <p>Potential reasons to suspect that a food worker is “infectious”: a) The food worker recently displays or admits a combination of foodborne disease symptoms (such as diarrhea, vomiting, nausea, fever, etc.) that may be similar to symptoms identified in those who are ill in the outbreak investigation; b) If a food worker’s household member exhibits similar symptoms directly preceding the outbreak; c) The food worker tested positive for a foodborne pathogen; d) Other epidemiologically- or environmentally-linked reasons.</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • Epidemiological or environmental investigation determines that an infectious food worker contaminates food with his/her hands but is unable to determine whether or not actual bare-hand contact or glove-hand contact contaminated the food. • In norovirus outbreaks, an ill food worker’s aerosolized vomitus contaminates ready-to-eat food. <p><u>Notable Exceptions</u></p> <p>None.</p>
Code	Factor	Description
C13	Foods contaminated by non-food handler / worker / preparer who is suspected to be infectious	<p><u>Title</u> C13 – Foods contaminated by non-food handler/worker/preparer who is suspected to be infectious</p> <p><u>Definition/Explanation</u> A person other than a food handler/worker/preparer who is suspected to be infectious, contaminates ready-to-eat foods that are later consumed by other persons, resulting in spread of the illness.</p> <p>A “non-food handler/worker/preparer” is considered to be any person who is not directly involved in the handling or preparation of the food prior to service.</p> <p>The term “infectious” is an all-inclusive term used to describe all persons who are colonized by, infected with, a carrier of, or ill due to a pathogen.</p> <p>Potential reasons to suspect that a non-food worker is “infectious”: a) The non-food worker recently displays or admits a combination of foodborne disease symptoms (such as diarrhea, vomiting, nausea, fever, etc.) that may be similar to symptoms identified in those who are ill in the outbreak investigation; b) If a non-food worker’s household member exhibits similar symptoms directly preceding the outbreak; c) The non-food worker tested positive for a foodborne pathogen; d) Other epidemiologically- or environmentally-linked reasons.</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • This is a typical situation when an ill person attends an event and contaminates ready-to eat-foods in a buffet

		<p>line by handling food prior to someone else consuming it. The original ill person is identified as a source of the pathogen.</p> <ul style="list-style-type: none"> • Pizza is prepared by a healthy food worker and arrives pathogen-free. A mother (a non-food worker) rearranges pizza slices onto plates before serving the slices to a group of children at a birthday party (regardless of whether it is taking place as a private party where the pizza has been ordered in or if the party is taking place in a restaurant). These children subsequently develop foodborne illness and the mother is identified as a source of the pathogen. <p><u>Notable Exceptions</u> None.</p>
Code	Factor	Description
C14	Storage in contaminated environment	<p><u>Title</u> C14 – Storage in contaminated environment</p> <p><u>Definition/Explanation</u> Storage in a contaminated environment (such as a store room or refrigerator) leads to contamination of the food vehicle or an ingredient in the vehicle.</p> <p>This usually involves storage of dry foods in an environment where contamination is likely from overhead drippage, flooding, airborne contamination, access of insects or rodents, and other situations conducive to contamination.</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • A leaky roof permits condensation to seep into a walk-in refrigerator and contaminate food stored in it. <p><u>Notable Exceptions</u> This contributing factor only applies to stored foods contaminated directly by environmental sources in the storage environment, not cross-contamination by other ingredients.</p>

Code	Factor	Description
C15	Other source of contamination	<p>Title C15 – Other source of contamination</p> <p>Definition/Explanation A form of contamination that does not fit into the above categories; the factor should be specified in the “Remarks” section at the end of the report.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Food in an uncovered bowl contaminated by flies • Food that is being washed/soaked in a food preparation sink is contaminated by sewage backflow from the sink’s pipes <p>Notable Exceptions None.</p>
Code	Factor	Description
C-N/A	Contamination Factors - Not Applicable	<p>Title C-N/A – Contamination Factors - Not Applicable</p> <p>Definition/Explanation C-N/A is utilized if contamination factors were not related to the type of etiologic agent involved in the outbreak. C-N/A would rarely, if ever, be cited.</p> <p>If no contamination factors were identified, then leave all contamination factors blank. Then, please explain why contamination factors could not be identified in the “Remarks” section at the end of this report.</p>

<p align="center">Proliferation/Amplification Factors (<i>bacterial outbreaks only</i>)</p> <p align="center">Factors that allow proliferation of the etiologic agents; proliferation factors relate to how bacterial agents were able to increase in numbers and/or produce toxic products prior to the vehicle being ingested.</p>		
Code	Factor	Description
P1	Food preparation practices that support proliferation of pathogens (<i>during food preparation</i>)	<p>Title P1 – Food preparation practices that support proliferation of pathogens (<i>during food preparation</i>)</p> <p>Definition/Explanation During food preparation, one or more improper procedures occurred (such as improper or inadequate thawing) that allowed pathogenic bacteria and/or molds to multiply and generate to populations sufficient to cause illness or to elaborate toxins if toxigenic.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Improper thawing (such as allowing frozen food to thaw at room temperature or leaving frozen foods in standing water for prolonged periods) allows pathogens on the surface of the food to multiply and generate • Prolonged preparation time (such as prolonging preparation time by preparing too many foods at the same time) allows pathogens to multiply and generate <p>Notable Exceptions None.</p>
Code	Factor	Description
P2	No attempt was made to control the temperature of implicated food or the length of time food was out of temperature control (<i>during food service or display of food</i>)	<p>Title P2 – No attempt was made to control the temperature of implicated food or the length of time food was out of temperature control (<i>during food service or display of food</i>)</p> <p>Definition/Explanation During food service or display of food, there was no attempt made to control the temperature of the implicated food or no attempt was made to regulate the length of time food was out of temperature control.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Leaving foods out at ambient temperature for a prolonged time at a church supper • No time or temperature control on a buffet line <p>Notable Exceptions None.</p>

Code	Factor	Description
P3	Improper adherence of approved plan to use Time as a Public Health Control	<p>Title P3 – Improper adherence of approved plan to use Time as a Public Health Control</p> <p>Definition/Explanation Food was out of temperature control for more than the time allowed under an agreed-upon and pre-approved plan by a regulatory agency to use Time as a Public Health Control.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Foods are placed on a buffet table that is not capable of maintaining proper hot or cold temperatures. The establishment has a plan approved by a regulatory agency to use Time as a Public Health Control. The plan allows foods to be displayed for service on the buffet line at ambient temperature, and discarded after 4 hours. However, the food is held on the buffet table for longer than 4 hours (either inadvertently or intentionally). • A facility negotiates a plan to use Time as a Public Health Control with a regulatory agency; however, the facility improperly adheres to the plan because some of the dishes that the facility serves is traditionally held and served at room temperature longer than the time allowed in the approved plan. <p>Notable Exceptions None.</p>
P4	Improper cold holding due to malfunctioning refrigeration equipment	<p>Title P4 – Improper cold holding due to malfunctioning refrigeration equipment</p> <p>Definition/Explanation Malfunctioning refrigeration equipment (such as refrigerators that are improperly maintained or adjusted) causes foods to be held at an improper cold holding temperature.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Walk-in cooler malfunction causing elevated temperatures of food • The reach-in (or walk-in) refrigerator unit temperature is not monitored and stays consistently higher than 41°F (or 45°F) causing elevated temperatures of food • A broken or torn door gasket causes air leakage in a reach-in refrigerator and subsequently food remains above 41°F (or 45°F). <p>Notable Exceptions None.</p>

Code	Factor	Description
P5	Improper cold holding due to an improper procedure or protocol	<p>Title P5 – Improper cold holding due to an improper procedure or protocol</p> <p>Definition/Explanation Improper cold holding temperature occurs due to an improper procedure or protocol (such as an overloaded refrigerator or inadequately iced salad bar).</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Potentially hazard foods (PHF) such as tuna/egg salad are stacked above the top levels of the cold holding wells in a deli sandwich cold holding unit <p>Notable Exceptions None.</p>
P6	Improper hot holding due to malfunctioning equipment	<p>Title P6 – Improper hot holding due to malfunctioning equipment</p> <p>Definition/Explanation Equipment that is meant to be used for hot-holding malfunctions and causes foods to be held at an improper hot holding temperature.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • A steam table is improperly maintained or adjusted and causes food to be held at improper hot holding temperatures. <p>Notable Exceptions None.</p>
P7	Improper hot holding due to improper procedure or protocol	<p>Title P7– Improper hot holding due to improper procedure or protocol</p> <p>Definition/Explanation Improper hot holding temperature occurs due to an improper procedure or protocol.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • An inadequate number of Sterno cans are used for holding foods hot in chafing dishes • Exhausted Sterno cans are not replaced under chafing dishes which hold hot foods • Steam table was not turned on

		<p><u>Notable Exceptions</u> None.</p>
Code	Factor	Description
P8	Improper/slow cooling	<p><u>Title</u> P8 – Improper/slow cooling</p> <p><u>Definition/Explanation</u> Foods are refrigerated in large quantities or stored in devices where the temperature is poorly controlled allowing pathogens to multiply.</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • Foods are refrigerated in large quantities (i.e. in large masses or as large volumes of foods in containers), which does not allow proper cooling • Foods are stored in containers with tight-fitting lids, pans are stacked on top of others, or crowded storage in a refrigerator, all of which leads to inadequate air circulation and thus improper/slow cooling • Improperly cooling foods includes any procedures outside of these parameters: Cooling foods from 135°F to 70°F within 2 hours and cooling that food from 70°F to 41°F within the next 4 hours. <p><u>Notable Exceptions</u> None.</p>
Code	Factor	Description
P9	Prolonged cold storage	<p><u>Title</u> P9 – Prolonged cold storage</p> <p><u>Definition/Explanation</u> This situation is a concern for psychrotrophic pathogenic bacteria (e.g. <i>Listeria monocytogenes</i>, <i>Clostridium botulinum</i> type E, <i>Yersinia enterocolitica</i>, <i>Aeromonas hydrophila</i>) that multiply over sufficient time at ordinary refrigerator temperatures and generate to populations sufficient to cause illness or elaborate toxins if toxigenic (e.g. <i>C. botulinum</i>).</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • Holding foods (that have been prepared in a food-service establishment) in cold storage for more than 7 days • Holding open containers of commercially prepared foods for several weeks <p><u>Notable Exceptions</u> None.</p>

Code	Factor	Description
P10	Inadequate modified atmosphere packaging	<p>Title P10 – Inadequate modified atmosphere packaging</p> <p>Definition/Explanation Food was stored in a container which provided an anaerobic environment. These factors create conditions conducive to growth of anaerobic or facultative bacteria in foods held in hermetically sealed cans or in packages in which vacuums have been pulled or gases added. All anaerobic bacteria must have a low oxygen reduction potential to initiate growth, but this factor is restricted only to foods that are put into the sealed package or container.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Vacuum-packed fish • Salad in gas-flushed bag <p>Notable Exceptions None.</p>
Code	Factor	Description
P11	Inadequate processing (acidification, water activity, fermentation)	<p>Title P11 – Inadequate processing (acidification, water activity, fermentation)</p> <p>Definition/Explanation There are certain non-temperature-dependent processes (such as acidification, water activity, fermentation) that are designed to prevent proliferation of pathogens. However, if these processes are inadequate, pathogens will multiply and generate to populations sufficient to cause illness.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • 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 <p>Notable Exceptions None.</p>

Code	Factor	Description
P12	Other situations that promoted or allowed microbial growth or toxic production	<p>Title P12 – Other situations that promoted or allowed microbial growth or toxic production</p> <p>Definition/Explanation A factor that promotes growth, proliferation, amplification, or concentration of etiologic agents but that does not fit into any of the other defined categories; the factor should be specified in the “Remarks” section at the end of the report.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • A box of tomatoes was unknowingly contaminated by <i>Salmonella</i> prior to its arrival at a restaurant. Soon after the delivery, some of the tomatoes were served to customers but these customers did not become ill. However, some of the other tomatoes from the box were not served soon after delivery – instead, these intact tomatoes were allowed to ripen at room temperature for several days, which allowed the <i>Salmonella</i> to amplify. Customers who ate these room-ripened tomatoes became ill. Although allowing intact tomatoes to ripen at room temperature is not a Food Code violation, this process likely led to bacterial proliferation. <p>Notable Exceptions None.</p>
Code	Factor	Description
P-N/A	Proliferation/Amplification Factors - Not Applicable	<p>Title P-N/A – Proliferation/Amplification Factors - Not Applicable</p> <p>Definition/Explanation P-N/A is utilized if proliferation/amplification factors are not related to the type of etiologic agent involved in the outbreak. For example, proliferation/amplification factors would not be cited in a viral outbreak.</p> <p>If no proliferation/amplification factors were identified, then leave all proliferation/amplification factors blank. Then, please explain why proliferation/amplification factors could not be identified in the “Remarks” section at the end of this report.</p>

Survival Factors (<i>microbial outbreaks only</i>) Factors that allow survival or fail to inactivate the contaminant; survival factors refer to processes or steps that should have eliminated or reduced the microbial agent but did not because of one of these factors.		
Code	Factor	Description
S1	Insufficient time and/or temperature during cooking/heat processing	<p><u>Title</u> S1 – Insufficient time and/or temperature control during initial cooking/heat processing</p> <p><u>Definition/Explanation</u> The time/temperature exposure during initial heat processing or cooking was inadequate to kill the pathogens. This does not include inactivation of preformed heat-stable toxins. 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.</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • Insufficient time and/or temperature control for roasted meats/poultry, canned foods, pasteurization <p><u>Notable Exceptions</u> Citation of S1 does not include inactivation of preformed heat-stable toxins or destruction of bacterial spores during cooking.</p>
Code	Factor	Description
S2	Insufficient time and/or temperature during reheating	<p><u>Title</u> S2 – Insufficient time and/or temperature during reheating</p> <p><u>Definition/Explanation</u> The time/temperature exposure during reheating or heat processing of a previously cooked food (which has often been cooled, frequently, overnight) was inadequate to kill the pathogens. This does not include inactivation of preformed heat-stable toxins.</p> <p><u>Common Examples</u></p> <ul style="list-style-type: none"> • Reheating of sauces or roasts to a temperature insufficient to reduce the level of contamination to below an infectious dose. <p><u>Notable Exceptions</u> Citation of S2 does not include inactivation of preformed heat-stable toxins.</p>

Code	Factor	Description
S3	Insufficient time and/or temperature control during freezing	<p>Title S3 – Insufficient time and/or temperature control during freezing</p> <p>Definition/Explanation In order to ensure the destruction of certain parasites, some foods such as fish may be frozen before raw service. This factor is cited when there was insufficient time and/or temperature control during freezing.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Pacific red snapper is the implicated food in an outbreak of <i>Anisakis</i> infection. The snapper was not frozen before service in raw sushi or the investigation revealed that the time and temperature required to kill parasites (-31°F for 15 hours or 4°F for 7 days) was not utilized. <p>Notable Exceptions Freezing is currently utilized for parasite destruction in fish served raw. In the future if it is determined that freezing can be used for pathogen destruction in other situations, then this factor would be cited if established procedures are not implemented or implemented incorrectly.</p> <p>Some species of tuna are not susceptible to harboring 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.</p>
Code	Factor	Description
S4	Insufficient or improper use of chemical processes designed for pathogen destruction	<p>Title S4 – Insufficient or improper use of chemical processes designed for pathogen destruction</p> <p>Definition/Explanation There are certain chemical processes (such as acidification, salting, and cold smoking) that are designed to prevent survival of pathogens. However, if these processes are insufficient or improperly used, pathogens will survive.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Inadequate acidification (such as insufficient quantity or concentration of acid) of canned tomatoes results in pathogen survival • Inadequate cold smoking of meat (such as insufficient time of contact of the smoke with the meat) results in pathogen survival <p>Notable Exceptions None.</p>

Code	Factor	Description
S5	Other process failures that permit pathogen survival	<p>Title S5 – Other process failures that permit pathogen survival</p> <p>Definition/Explanation A form of survival that does not fit into the above categories; the factor should be specified in the “Remarks” section at the end of the report.</p> <p>Common Examples</p> <ul style="list-style-type: none"> • Failures of other processes (such as subjecting foods to irradiation, high pressure, drying conditions) that permits pathogens to survive. <p>Notable Exceptions None.</p>
Code	Factor	Description
S-N/A	Survival Factors - Not Applicable	<p>Title S-N/A – Survival Factors - Not Applicable</p> <p>Definition/Explanation S-N/A is utilized if survival factors were not related to the type of etiologic agent involved in the outbreak. For example, survival factors would not be cited in a scombroid toxin outbreak.</p> <p>If no survival factors were identified, then leave all survival factors blank. Then, please explain why proliferation/amplification factors could not be identified in the “Remarks” section at the end of this report.</p>