Appendix D: NORS Guidance for Contributing Factors (CF) in Foodborne Outbreak Reports

**Contributing Factors**

**Introduction**
Contributing factors (CFs) are defined as the 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.

**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.

**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.
### Contributing Factors

**How to Identify Contributing Factors in an Outbreak**

In a foodborne 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 #1:
After consideration of all epidemiological, laboratory, and environmental assessment information available for this outbreak, can any contributing factors for this outbreak be determined?

YES
One or more contributing factors could be identified.

NO
Contributing factors for this outbreak could not be identified.

Question #2:
Was an etiologic agent determined?

YES
A confirmed or suspected etiologic agent was determined.
(Proceed to Question #3)

NO
The etiologic agent was undetermined.

For unknown etiologic agents, it may be difficult to make a determination about the contributing factors to the outbreak. If a particular etiologic agent is suspected, follow the flowchart guidance for that agent. If no particular etiologic agent is suspected, select the appropriate contributing factors (if they could be determined) and make notes in the “Remarks” section as necessary. Otherwise, if no contributing factors could be determined, check the “Contributing Factors Unknown” box.

Action:
1. Check the “Contributing Factors Unknown” box.
2. Leave the remainder of the contributing factors section completely blank.
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 proliferation/amplification factors applicable to the outbreak? (They almost always should be for bacterial pathogens.)

- YES
  - Action: Select “C1–C15.”
- NO
  - Action: Select any contamination factors.

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

- YES
  - Action: Select all relevant proliferation/amplification factors: P1–P12.
- NO
  - Action: Do NOT select any proliferation/amplification factors.

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

- YES
  - Action: Select all relevant survival factors: S1–S6.
- NO
  - Action: Do NOT select any survival factors.

For an outbreak with confirmed/suspected bacterial etiology:
- Contamination factors are applicable but could not be determined.
- AND
  - Proliferation/amplification factors are applicable but could not be determined.
- AND
  - Survival factors are applicable but could not be determined…
  - THEN…

Action:
Check the “Contributing Factors Unknown” box.

Legend for Flowchart
- Guiding questions for flowchart
- Contributing Factors Unknown
- Etiologic Agent Undetermined/Unknown
- Double Arrow – Guiding questions #4A, #4B, and #4C must all be answered for each type of etiologic agent.
## Contributing Factors Unknown

<table>
<thead>
<tr>
<th>Code</th>
<th>Factor</th>
<th>Description</th>
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</thead>
</table>
| CF Unknown | Contributing Factors Unknown | **Title**

CF Unknown – Contributing Factors Unknown

**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.

## Contamination Factors

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

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<thead>
<tr>
<th>Code</th>
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</table>
| C1   | Toxic substance part of tissue     | **Title**

C1 – Toxic substance part of the tissue

**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.

**Common Examples**

- Mushroom poisoning due to consumption of toxic mushrooms
- Ciguatera fish poisoning due to consumption of tropical marine finfish which have bioaccumulated naturally-occurring ciguatera toxins through their diet
- Scombroid fish poisoning due to consumption of fish containing elevated levels of histamine 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.

**Notable Exceptions**

None.

| C2   | Poisonous substance intentionally / deliberately added | **Title**

C2 – Poisonous substance intentionally/deliberately added

**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.

**Common Examples**

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

**Notable Exceptions**

None.
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<th><strong>Code</strong></th>
<th><strong>Factor</strong></th>
<th><strong>Description</strong></th>
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<tbody>
<tr>
<td>C3</td>
<td>Poisonous substance accidentally / inadvertently added</td>
<td><strong>Title</strong>&lt;br&gt;C3 – Poisonous substance accidentally/inadvertently added&lt;br&gt;&lt;br&gt;<strong>Definition/Explanation</strong>&lt;br&gt;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.&lt;br&gt;&lt;br&gt;Misreading labels, resulting in either mistaking poisonous substances for foods or incorporating them into food mixtures, would also fall into this category.&lt;br&gt;&lt;br&gt;<strong>Common Examples</strong>&lt;br&gt;• Sanitizer or cleaning compound accidentally added to food&lt;br&gt;&lt;br&gt;<strong>Notable Exceptions</strong>&lt;br&gt;None.</td>
</tr>
<tr>
<td>C4</td>
<td>Addition of excessive quantities of ingredients that are toxic in large amounts</td>
<td><strong>Title</strong>&lt;br&gt;C4 – Addition of excessive quantities of ingredients that are toxic in large amounts&lt;br&gt;&lt;br&gt;<strong>Definition/Explanation</strong>&lt;br&gt;An approved ingredient in a food can be accidentally added in excessive quantities so as to make the food unacceptable for consumption.&lt;br&gt;&lt;br&gt;<strong>Common Examples</strong>&lt;br&gt;• Niacin poisoning in bread&lt;br&gt;• Too great an amount of nitrites in cured meat&lt;br&gt;• Too great an amount of ginger powder in gingersnaps&lt;br&gt;&lt;br&gt;<strong>Notable Exceptions</strong>&lt;br&gt;None.</td>
</tr>
<tr>
<td>C5</td>
<td>Toxic container</td>
<td><strong>Title</strong>&lt;br&gt;C5 – Toxic container&lt;br&gt;&lt;br&gt;<strong>Definition/Explanation</strong>&lt;br&gt;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.&lt;br&gt;&lt;br&gt;<strong>Common Examples</strong>&lt;br&gt;• Galvanized containers with acid food&lt;br&gt;• A toxic metal (e.g., zinc coated) container used to store highly acid foods&lt;br&gt;&lt;br&gt;<strong>Notable Exceptions</strong>&lt;br&gt;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.</td>
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<td><strong>CODE</strong></td>
<td><strong>FACTOR</strong></td>
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| C6       | Contaminated raw product – food was intended to be consumed after a kill step | **Title**  
C6 – Contaminated raw product – food was intended to be consumed after a kill step  

**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.  

Note: Lab confirmation or a formal traceback can support or confirm the identification of this contributing factor (e.g., a traceback identifies a flock, herd, or farm as the source of the pathogen). If 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.

**Common Examples**  
- 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 Salmonella, which was then unintentionally undercooked.

**Notable Exceptions**  
None.

| C7       | Contaminated raw product – food was intended to be consumed raw or undercooked/under-processed | **Title**  
C7 – Contaminated raw product – food was intended to be consumed raw or undercooked/under-processed  

**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.

**Common Examples**  
- A hamburger or steak ordered to be prepared rare  
- Raw milk  
- Raw oysters or other shellfish  
- Raw produce  
- Unpasteurized cider or juices  
- 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

**Notable Exceptions**  
None.
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<th>Code</th>
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</table>
| C8   | Foods originating from sources shown to be contaminated or polluted (such as a growing field or harvest area) | **Title**  
C8 – Foods originating from sources shown to be contaminated or polluted (such as a growing field or harvest area)  

**Definition/Explanation**  
Foods that originated from sources shown to be contaminated or polluted (such as a growing field or harvest area).  

Note: 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.  

**Common Examples**  
- Shellfish from sewage-polluted waters or closed beds  
- Crops watered by contaminated irrigation water  
- Produce grown in contaminated soil  

**Notable Exceptions**  
None.

| C9   | Cross-contamination of ingredients (cross-contamination does not include ill food workers) | **Title**  
C9 – Cross-contamination of ingredients (cross-contamination does not include ill food workers)  

**Definition/Explanation**  
The pathogen was transferred to the vehicle by contact with contaminated worker hands, equipment, or utensils; drippings or spillage. If worker hands were the mode of contamination, the worker was not infected with or a carrier of the pathogen.  

**Common Examples**  
- Contaminated raw poultry was prepared on a cutting board, and later, a ready-to-eat food was cross-contaminated because it was prepared on this same cutting board without intervening cleaning.  
- 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.  

**Notable Exceptions**  
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).
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<th>Code</th>
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<tbody>
<tr>
<td>C10</td>
<td>Bare-hand contact by a food handler/worker/preparer who is suspected to be infectious</td>
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</table>

**Title**
C10 – Bare-hand contact by a food handler/worker/preparer who is suspected to be infectious

**Definition/Explanation**
A food worker, who is suspected to be infectious, uses his/her bare hands to touch/prepare foods that are not subsequently cooked.

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.

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.

Note: 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.

**Common Examples**
- This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.

**Notable Exceptions**
None.
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<tr>
<th>Code</th>
<th>Factor</th>
<th>Description</th>
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</table>
| C11  | Glove-hand contact by a food handler/worker | **Title**
C11 – Glove-hand contact by a food handler/worker/preparer who is suspected to be infectious

**Definition/Explanation**
A food worker, who is suspected to be infectious, uses his/her gloved-hands to touch/prepare foods that are not subsequently cooked.

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.

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.

Note: 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.

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.

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

**Notable Exceptions**
None.
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</table>
| C12  | Other mode of contamination (excluding cross-contamination) by a food handler/worker/preparer who is suspected to be infectious | **Title**
C12 – Other mode of contamination (excluding cross-contamination) by a food handler/worker/preparer who is suspected to be infectious

**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.

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.

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.

**Common Examples**
- 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.

**Notable Exceptions**
None.
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<th>Code</th>
<th>Factor</th>
<th>Description</th>
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</table>
| C13  | Foods contaminated by non-food handler/worker/preparer who is suspected to be infectious | **Title**
C13 – Foods contaminated by non-food handler/worker/preparer who is suspected to be infectious

**Definition/Explanation**
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.

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.

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.

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.

**Common Examples**
- This is a typical situation when an ill person attends an event and contaminates ready-to-eat foods in a buffet line by handling food prior to someone else consuming it. The original ill person is identified as a source of the pathogen.
- 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.

**Notable Exceptions**
None.

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<th>Code</th>
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| C14  | Storage in contaminated environment | **Title**
C14 – Storage in contaminated environment

**Definition/Explanation**
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.

This usually involves storage of dry foods in an environment where contamination is likely from overhead dripping, flooding, airborne contamination, access of insects or rodents, and other situations conducive to contamination.

**Common Examples**
- A leaky roof permits condensation to seep into a walk-in refrigerator and contaminate food stored in it.

**Notable Exceptions**
This contributing factor only applies to stored foods contaminated directly by environmental sources in the storage environment, not cross-contamination by other ingredients.
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<th><strong>Code</strong></th>
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</table>
| C15      | Other source of contamination | **Title**  
C15 – Other source of contamination  
**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.  
**Common Examples**  
• 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  
**Notable Exceptions**  
None. |
| C-N/A    | Contamination Factors - Not Applicable | **Title**  
C-N/A – Contamination Factors - Not Applicable  
**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.  
If no contamination factors were identified, then leave all contamination factors blank. |
**PROLIFERATION/AMPLIFICATION FACTORS (BACTERIAL OUTBREAKS ONLY)**

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.

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| P1   | Food preparation practices that support proliferation of pathogens (during food preparation) | **Title**  
P1 – Food preparation practices that support proliferation of pathogens (during food preparation)  
**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.  
**Common Examples**  
• 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  
**Notable Exceptions**  
None. |
| P2   | No attempt was made to control the temperature of implicated food or the length of time food was out of temperature control (during food service or display of food) | **Title**  
P2 – No attempt was made to control the temperature of implicated food or the length of time food was out of temperature control (during food service or display of food)  
**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.  
**Common Examples**  
• Leaving foods out at ambient temperature for a prolonged time at a church supper  
• No time or temperature control on a buffet line  
**Notable Exceptions**  
None. |
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<tr>
<th>Code</th>
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<th>Description</th>
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</table>
| P3   | Improper adherence of approved plan to use Time as a Public Health Control | **Title**
P3 – Improper adherence of approved plan to use Time as a Public Health Control

**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.

**Common Examples**
- 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.

**Notable Exceptions**
None.

| P4   | Improper cold holding due to malfunctioning refrigeration equipment | **Title**
P4 – Improper cold holding due to malfunctioning refrigeration equipment

**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.

**Common Examples**
- 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)

**Notable Exceptions**
None.

| P5   | Improper cold holding due to an improper procedure or protocol | **Title**
P5 – Improper cold holding due to an improper procedure or protocol

**Definition/Explanation**
Improper cold holding temperature occurs due to an improper procedure or protocol (such as an overloaded refrigerator or inadequately iced salad bar).

**Common Examples**
- 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

**Notable Exceptions**
None.
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<tbody>
<tr>
<td>P6</td>
<td>Improper hot holding due to malfunctioning equipment</td>
<td><strong>Title</strong>&lt;br&gt;P6 – Improper hot holding due to malfunctioning equipment&lt;br&gt;&lt;br&gt;<strong>Definition/Explanation</strong>&lt;br&gt;Equipment that is meant to be used for hot-holding malfunctions and causes foods to be held at an improper hot holding temperature.&lt;br&gt;&lt;br&gt;<strong>Common Examples</strong>&lt;br&gt;• A steam table is improperly maintained or adjusted and causes food to be held at improper hot holding temperatures&lt;br&gt;&lt;br&gt;<strong>Notable Exceptions</strong>&lt;br&gt;None.</td>
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<td>P7</td>
<td>Improper hot holding due to improper procedure or protocol</td>
<td><strong>Title</strong>&lt;br&gt;P7 – Improper hot holding due to improper procedure or protocol&lt;br&gt;&lt;br&gt;<strong>Definition/Explanation</strong>&lt;br&gt;Improper hot holding temperature occurs due to an improper procedure or protocol.&lt;br&gt;&lt;br&gt;<strong>Common Examples</strong>&lt;br&gt;• An inadequate number of Sterno cans are used for holding foods hot in chafing dishes&lt;br&gt;• Exhausted Sterno cans are not replaced under chafing dishes which hold hot foods&lt;br&gt;• Steam table was not turned on&lt;br&gt;&lt;br&gt;<strong>Notable Exceptions</strong>&lt;br&gt;None.</td>
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<td>P8</td>
<td>Improper/slow cooling</td>
<td><strong>Title</strong>&lt;br&gt;P8 – Improper/slow cooling&lt;br&gt;&lt;br&gt;<strong>Definition/Explanation</strong>&lt;br&gt;Foods are refrigerated in large quantities or stored in devices where the temperature is poorly controlled allowing pathogens to multiply.&lt;br&gt;&lt;br&gt;<strong>Common Examples</strong>&lt;br&gt;• Foods are refrigerated in large quantities (e.g., in large masses or as large volumes of foods in containers), which does not allow proper cooling&lt;br&gt;• 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&lt;br&gt;• 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&lt;br&gt;&lt;br&gt;<strong>Notable Exceptions</strong>&lt;br&gt;None.</td>
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<td><strong>Code</strong></td>
<td><strong>Factor</strong></td>
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| **P9**  | Prolonged cold storage | **Title**  
P9 – Prolonged cold storage  

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

**Common Examples**  
- 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  

**Notable Exceptions**  
None.  

| **P10** | Inadequate modified atmosphere packaging | **Title**  
P10 – Inadequate modified atmosphere packaging  

**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.  

**Common Examples**  
- Vacuum-packed fish  
- Salad in gas-flushed bag  

**Notable Exceptions**  
None.  

| **P11** | Inadequate processing (acidification, water activity, fermentation) | **Title**  
P11 – Inadequate processing (acidification, water activity, fermentation)  

**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.  

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

**Notable Exceptions**  
None.  

updated 9/9/2016
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| P12  | Other situations that promoted or allowed microbial growth or toxic production | **Title**  
P12 – Other situations that promoted or allowed microbial growth or toxic production  

**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.  

**Common Examples**  
• A box of tomatoes was unknowingly contaminated by Salmonella 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 Salmonella 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.  

**Notable Exceptions**  
None.

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| P-N/A| Proliferation/Amplification Factors - Not Applicable | **Title**  
P-N/A – Proliferation/Amplification Factors - Not Applicable  

**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.  

If no proliferation/amplification factors were identified, then leave all proliferation/amplification factors blank.
**Survival Factors (Microbial Outbreaks Only)**

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.

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| S1   | Insufficient time and/or temperature during cooking/heat processing | **Title**  
S1 – Insufficient time and/or temperature control during initial cooking/heat processing  

**Definition/Explanation**  
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.  

**Common Examples**  
- Insufficient time and/or temperature control for roasted meats/poultry, canned foods, pasteurization  

**Notable Exceptions**  
Citation of S1 does not include inactivation of preformed heat-stable toxins or destruction of bacterial spores during cooking.

| S2   | Insufficient time and/or temperature during reheating | **Title**  
S2 – Insufficient time and/or temperature during reheating  

**Definition/Explanation**  
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.  

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

**Notable Exceptions**  
Citation of S2 does not include inactivation of preformed heat-stable toxins.

| S3   | Insufficient time and/or temperature control during freezing | **Title**  
S3 – Insufficient time and/or temperature control during freezing  

**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.  

**Common Examples**  
- Pacific red snapper is the implicated food in an outbreak of *Anisakis* 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.  

**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. 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.
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| **S4** | Insufficient or improper use of chemical processes designed for pathogen destruction | **Title**<br>S4 – Insufficient or improper use of chemical processes designed for pathogen destruction  
**Definition/Explanation**<br>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.  
**Common Examples**<br>• 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  
**Notable Exceptions**<br>None. |
| **S5** | Other process failures that permit pathogen survival | **Title**<br>S5 – Other process failures that permit pathogen survival  
**Definition/Explanation**<br>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.  
**Common Examples**<br>• Failures of other processes (such as subjecting foods to irradiation, high pressure, drying conditions) that permits pathogens to survive  
**Notable Exceptions**<br>None. |
| **S-N/A** | Survival Factors - Not Applicable | **Title**<br>S-N/A – Survival Factors - Not Applicable  
**Definition/Explanation**<br>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. |