Contributing Factor Definitions 2009-2021

NEARS participants started using <u>revised contributing factor definitions</u> as of January 1, 2022, for outbreaks occurring in 2022 or later. The 2009–2021 definitions are still available for reporting outbreaks that started before 2022.

Staff from CDC and the Food and Drug Administration (FDA) developed these contributing factors to show how foodborne illness outbreaks evolve.

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Contamination Factors

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

C1 Toxic substance part of the tissue (e.g., ciguatera): 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.

Examples of this type of contributing factor include ciguatera fish poisoning due to consumption of marine fin fish or mushroom poisoning due to consumption of toxic mushrooms.

C2 Poisonous substance intentionally/deliberately added (e.g., cyanide or phenolphthalein added to cause illness): A poisonous substance intentionally or 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.

This contributing factor only applies to poisonous substances, not to physical substances added to food.

C3 Poisonous substance accidentally/inadvertently added (e.g., sanitizer or cleaning compound): A poisonous substance or chemical agent accidentally/inadvertently added to the vehicle. This addition typically occurs at the time of preparation or packaging of the vehicle.

Examples of this type of contributing factor include sanitizer or cleaning compound added to food or chemicals that reach foods from spillage or indiscriminate spraying. Misreading labels, resulting in either mistaking poisonous substances for foods or incorporating them into food mixtures, also falls into this category.

C4 Addition of excessive quantities of ingredients that are toxic in large amounts (e.g., niacin poisoning in bread): An approved ingredient in a food but accidentally added in excessive quantities so as to make the food unacceptable for consumption.

Examples of this type of contributing factor include excessive amounts of nitrites in cured meat or excessive amounts of ginger powder in gingersnaps.

C5 Toxic container (e.g., galvanized containers with acid foods): Container or pipe holding or conveying 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.

One example of this type of contributing factor is a toxic metal (e.g., zinc coated) container used to store highly acidic foods.

For this contributing factor, there may be confusion between foodborne outbreaks and waterborne outbreaks. If the outbreak is waterborne, the contributing factors should be listed in the waterborne section, not in this foodborne section. In general, waterborne disease included contamination occurring in the source water or in the treatment or distribution of water to the end consumer. For example,

- If water enters a contaminated drink mix/soda 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.
- If ice is made with contaminated water—it's waterborne and should not be entered in the foodborne section.
- If ice is already made and then it becomes contaminated because it was stored in a toxic container—it is a foodborne outbreak and it would be appropriate to list *C5* as a contributing factor.
- **C6 Contaminated raw product—food was intended to be consumed after a kill step:** 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 the food processing step was insufficient to lower the levels of the pathogen below an infectious dose.

Examples of this type of contributing factor include a hamburger that was ordered well-done or medium-well but subsequently undercooked when it arrived at final preparation or raw chicken that was contaminated with *Salmonella*, which was then unintentionally undercooked.

C7 Contaminated raw product—food was intended to be consumed raw or

undercooked/underprocessed (e.g., raw shellfish, produce, eggs): 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 that does not ensure pathogen destruction. Mild heating means heated to time- temperature exposures insufficient to kill vegetative forms of pathogenic bacteria or denature proteins.

Examples of this type of contributing factor include mildly heated hollandaise sauce containing raw egg yolk, a hamburger or steak ordered to be prepared rare, raw milk, raw oysters or other shellfish, raw produce, or unpasteurized cider or juices.

C8 Foods originating from sources shown to be contaminated or polluted (such as a growing field or harvest area) (e.g., shellfish): Foods obtained from sources shown to be contaminated, such as shellfish from sewage-polluted waters, crops watered by contaminated irrigation water, or produce grown in contaminated soil.

<u>Note</u>: Formal trace back 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*.

C9 Cross-contamination of ingredients (does not include ill food workers): Pathogen transferred to the vehicle by contact with contaminated worker hands, equipment, or utensils or by drippage or spillage. If worker hands were the mode of contamination, the worker was not infected with or a carrier of the pathogen.

Examples of this type of contributing factor include

- Contaminated raw poultry was prepared on a cutting board; 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; subsequently, a ready-to-eat food was cross-contaminated because the worker's hands touched this ready-to-eat food without intervening handwashing.
- Cloths, sponges, and other cleaning aids were used to clean equipment that processed contaminated raw foods. Before their 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.

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, it should be cited in *C14*.

C10 Bare-hand contact by a food handler/worker/preparer who is suspected to be infectious (e.g., with ready-to-eat-food): A food worker suspected to be infectious uses his or her bare hands to touch or 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. This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.

Only cite *C10* 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, cite *C12* instead.

C11 Glove-hand contact by a food handler/worker/preparer who is suspected to be infectious (e.g., with ready-to-eat-food): A food worker suspected to be infectious uses his or her gloved hands to touch or 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. This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.

Only cite *C11* 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, cite *C12* instead.

C12 Other mode of contamination (excluding cross-contamination) by a food

handler/worker/preparer who is suspected to be infectious: A food worker suspected to be infectious contaminates the food by another mode of contamination other than bare-hand contact or glove-hand contact, or an epidemiological/environmental investigation determines that an infectious food worker contaminates food with his or 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.

Examples of this contributing factor include

- 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.
- **C13** Foods contaminated by non-food handler/worker/preparer who is suspected to be infectious: A person other than a food handler/worker/preparer 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 any person not directly involved in the handling or preparation of food before service. 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 before someone else consumes it. The original ill person is identified as a source of the pathogen.

One example of this type of contributing factor is a when healthy food worker prepares pizza, which 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 setting—it could be at a home or a restaurant). These children subsequently develop foodborne illness and the mother is identified as a source of the pathogen.

C14 Storage in contaminated environment (e.g., storeroom, refrigerator): Storage in a contaminated environment (such as a storeroom or refrigerator) leads to contamination of the food vehicle or an ingredient in the vehicle. This contributing factor only applies to stored foods that were contaminated directly by environmental sources, not contamination by other foods. 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.

This contributing factor only applies to food contaminated during storage, not foods contaminated during preparation or service.

C15 Other source of contamination (please describe): A form of contamination that does not fit into the above categories. Physical substances added intentionally or deliberately also fall into this category. Objects can get into food either from lack of removal of seeds or other hard particles or from objects in the soil.

Examples of this contributing factor include glass shards intentionally or deliberately added to food, food in an uncovered bowl contaminated by flies, or food being washed or soaked in a food preparation sink that gets contaminated by sewage backflow from the sink's pipes.

Proliferation/Amplification Factors (Bacterial outbreaks only)

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

P1 Food preparation practices that support proliferation of pathogens (during food preparation): 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.

Examples of this type of contributing factor include

- 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.
- 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): During food service or display of food, no attempt was 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.

Examples of this type of contributing factor include leaving foods out at ambient temperature for a prolonged time at a church supper or no time and temperature control on a buffet line.

P3 Improper adherence of approved plan to use time as a public health control: Food out of temperature control for more than the time allowed under an agreed-upon and preapproved plan by a regulatory agency to use time as a public health control.

Examples of this type of contributing factor include

- 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, then 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 with a regulatory agency to use time as a public health control. The facility improperly adheres to the plan because some of the dishes that the facility serves are traditionally held and served at room temperature longer than the time allowed in the approved plan.
- **P4** Improper cold holding due to malfunctioning refrigeration equipment: Malfunctioning refrigeration equipment (such as improperly maintained or adjusted refrigerators) causes foods to be held at an improper cold holding temperature or walk-in cooler malfunction causes elevated temperatures of food.

Examples of this type of contributing factor include

- The reach-in (or walk-in) refrigerator unit temperature is not monitored and stays consistently higher than 41°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.
- **P5** Improper cold holding due to an improper procedure or protocol: Improper cold holding temperature because of an improper procedure or protocol (such as an overloaded refrigerator or inadequately iced salad bar).

Examples of this type of contributing factor include potentially hazardous foods such as tuna salad or egg salad stacked above the top levels of the cold holding wells in a deli sandwich cold holding unit.

P6 Improper hot holding due to malfunctioning equipment: Equipment meant to be used for hotholding malfunctions and causes foods to be held at an improper hot holding temperature.

Examples of this type of contributing factor include a steam table that is improperly maintained or adjusted and causes food to be held at improper hot holding temperatures.

P7 Improper hot holding due to improper procedure or protocol: Improper hot holding temperature because of an improper procedure or protocol.

Examples of this type of contributing factor include

- An inadequate number of Sterno cans are used for holding foods hot in chafing dishes.
- Exhausted Sterno cans are not replaced under chafing dishes that hold hot foods.
- Steam table was not turned on.
- **P8** Improper/slow cooling: Foods refrigerated in large quantities or stored in devices where temperature is poorly controlled allows pathogens to multiply. Improperly cooling foods are those

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.

Examples of this type of contributing factor include

- Foods are refrigerated in large quantities (i.e., in large masses or as large volumes of foods in containers) that do not allow proper cooling.
- Foods are stored in containers with tight-fitting lids, leading to inadequate air circulation and thus improper cooling.
- **P9 Prolonged cold storage:** 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*).

Examples of this type of contributing factor include

- Holding foods prepared in a food-service establishment in cold storage for more than 7 days.
- Holding open containers of commercially prepared foods for several weeks.
- **P10** Inadequate modified atmosphere packaging (e.g., vacuum-packed fish, salad in gas- flushed bag): Food stored in a container that 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.

P11 Inadequate processing (e.g., acidification, water activity, fermentation): Inadequate nontemperature-dependent processes (such as acidification, water activity, fermentation) that do not prevent proliferation of pathogens, which multiply and generate populations sufficient to cause illness.

Examples of this type of contributing factor include

- 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.
- **P12** Other situations that promote or allow microbial growth or toxin production (please describe): A factor that promotes growth, proliferation, amplification, or concentration of etiologic agents but does not fit into any of the other defined categories; the factor should be specified.

One examples of this type of contributing factor is a box of tomatoes that was unknowingly contaminated by *Salmonella* before its arrival at a restaurant. Soon after the delivery, some of the

tomatoes were served to customers but these customers did not become ill. Some of the other tomatoes from the box were not served soon after delivery—instead, these tomatoes were allowed to ripen at room temperature for several days, which allowed the *Salmonella* to amplify. Customers who ate the 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.

Survival Factors (Primarily bacterial outbreaks)

Factors that allow survival or fail to destroy or inactivate the contaminant; survival factors refers to processes or steps that should have eliminated or reduced the microbial agent but did not.

S1 Insufficient time and/or temperature during cooking/heat processing (e.g., roasted meats/poultry, canned foods, pasteurization): Time/temperature exposure during initial heat processing or cooking inadequate to kill the pathogen under investigation. In reference to <u>cooking</u>, it refers to the destruction of vegetative forms of bacteria, viruses, and parasites, but not bacterial spores and sometimes not bacterial toxins (e.g., heat resistant ones). If the food under investigation was retorted, then spore-forming bacteria would be included.

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 (e.g., sauces, roasts): Time/temperature exposure during reheating or heat processing of a previously cooked or heated food (which has often been cooled overnight) inadequate to kill the pathogens.

S2 does not include inactivation of preformed heat-stable toxins.

S3 Insufficient time and/or temperature control during freezing: Insufficient time and/or temperature control during freezing of foods such as fish, which may be frozen before raw service.

One example of this type of contributing factor is when there is insufficient time and/or temperature control during freezing: 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 used.

Freezing is currently used 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, this factor would be cited if established procedures are not implemented or are implemented incorrectly. Some species of tuna are not susceptible to harboring parasites of concern, so 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 citing *S3*.

S4 Insufficient or improper use of chemical processes designed for pathogen destruction: Insufficient or improperly used chemical processes (such as acidification, salting, and cold smoking) allow pathogens to survive.

Examples of this type of contributing factor include

- 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.
- S5 Other process failures that permit the agent to survive (please describe): Other forms of survival. A form of survival that does not fit into the above categories; the factor should be specified. Failures of other processes (such as subjecting foods to irradiation, high pressure, drying conditions) that then permits pathogens to survive. Specify the survival factor.