Attachment 2- FDA/CDC list of Contributing Factors to Foodborne Illness Outbreaks

FDA/CDC List of Contributing Factors to Foodborne Illness Outbreaks

The following table list the most common contributing factors to foodborne illness outbreaks as identified, defined, and labeled by the FDA and CDC. These contributing factors are grouped into three categories: contamination, proliferation, and survival.

Contamination Factors Contamination factors are those that contribute to bacteria, virus, toxin or parasite getting into or onto food. Examples of contamination factors include a contaminated ingredient entering a facility, cross-contamination of raw and ready-to-eat foods, and worker contamination of food due to bare-handed contact with the food when the worker was ill.	
C1	**Toxic substance part of the tissue (e.g. ciguatera): Natural toxin.** 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 include: Ciguatera fish poisoning due to consumption of marine finfish and mushroom poisoning due to consumption of toxic mushroom.
C2	**Poisonous substance intentionally/deliberately added (e.g. cyanide or phenolphthalein added to cause illness):** 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. This contributing factor only applies to poisonous substances, not physical substances added to food.
C3	**Poisonous substance accidentally / inadvertently added (e.g. sanitizer or cleaning compound):** 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. Examples 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, would also fall 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 can be accidentally added in excessive quantities so as to make the food unacceptable for consumption. Examples include too great an amount of nitrites in cured meat or too great an amount of ginger powder in gingersnaps.
C5	**Toxic container (e.g. galvanized containers with acid foods):** The container or pipe 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. An example of this is a toxic metal (e.g. zinc coated) container used to store highly acid foods.
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 this food processing step was insufficient to lower the levels of the pathogen below an infectious dose. Examples include: a hamburger was ordered well-done or medium-well, but subsequently undercooked when it arrived at final preparation or raw chicken was contaminated with Salmonella, which was then unintentionally undercooked. Note: 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).

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C7	**Contaminated raw product:** food was intended to be consumed raw or undercooked/ under-processed (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 which does not ensure pathogen destruction. An example is mildly heated (i.e. heated to time-temperature exposures insufficient to kill vegetative forms of pathogenic bacteria or denature proteins) hollandaise sauce containing raw egg yolk, a hamburger or steak ordered to be prepared "rare", raw milk, raw oysters or other shellfish, raw produce, 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. *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.
C9	**Cross-contamination of ingredients (cross-contamination does *not* include ill food workers):** 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. 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. 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).
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, 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. 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. This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins.
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, 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. This is a typical situation that precedes outbreaks caused by norovirus or staphylococcal enterotoxins. 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.
C12	**Other mode of contamination (excluding cross-contamination) by a food handler/worker/preparer who is suspected to be infectious:** A food worker, who is suspected to be infectious, contaminates the food by another mode of contamination other than bare-

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	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. 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 that is suspected to be infectious:** 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. Example: 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.
C14	**Storage in contaminated environment (e.g. store room, refrigerator):** 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 contributing factor only applies to stored foods that were contaminated directly by environmental sources, not contamination by other foods. Example: 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:** A form of contamination that does not fit into the above categories. In addition, physical substances that are intentionally/deliberately added would fall into this category. Although there is seldom an attempt to add sharp or hard objects to foods, objects can reach foods either from lack of removal of seeds or other hard particles or from the presence of objects in the soil. For example, glass shards intentionally/ deliberately added to food, 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.

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Proliferation Factors *Proliferation/amplification factors are those that contribute to bacteria or toxins increasing in number and/or producing toxic products prior to the food being eaten. Examples of proliferation factors include improper cold or hot holding of foods or inadequate processing such as acidification, water activity, or fermentation. These factors relate only to bacterial outbreaks.*	
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. 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, 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. Example: leaving foods out at ambient temperature for a prolonged time at a church supper. No time or temperature control on a buffet line.
P3	**Improper adherence of approved plan to use Time as a Public Health Control:** 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. 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). OR, 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 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 refrigerators that are improperly maintained or adjusted) causes foods to be held at an improper cold holding temperature. 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 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 occurs due to an improper procedure or protocol (such as an overloaded refrigerator or inadequately iced salad bar). For example, 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**.**
P6	**Improper hot holding due to malfunctioning equipment:** Equipment that is meant to be used for hot-holding malfunctions and causes foods to be held at an improper hot holding temperature. Example: a steam table 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 occurs due to an improper procedure or protocol. Example: 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.

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P8	**Improper/slow cooling**: Foods are refrigerated in large quantities or stored in devices where the temperature is poorly controlled allowing pathogens to multiply. Examples: 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 that leads to inadequate air circulation and thus improper 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.
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 include: Holding foods (that have been prepared in a food-service establishment) in cold storage for more than 7 days or 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 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.
P11	**Inadequate processing (e.g. acidification, water activity, fermentation):** 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. Examples include: insufficient acidification (low concentration of acidic ingredients) in home canned foods, insufficiently low water activity (low concentration of salt) in smoked/salted fish, and 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 toxic production:** A factor that promotes growth, proliferation, amplification, or concentration of etiologic agents but that does not fit into any of the other defined categories. Example: a box of tomatoes was unknowingly / unintentionally 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.

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Survival Factors *Survival factors are those that contribute to bacteria, viruses, or parasites surviving in food. Specifically, they refer to processes or steps which would have eliminated or reduced the bacteria, virus or parasite in the food if conducted properly. Examples of survival factors include insufficient time and/or temperature during cooking/heat processing, insufficient time and/or temperature during reheating, and insufficient time and/or temperature control during freezing to kill parasites. While survival factors primarily relate to bacterial and parasitic outbreaks, under limited circumstances they may be appropriately cited in viral outbreaks as well.*	
S1	**Insufficient time and/or temperature during cooking/heat processing** (e.g. roasted meats/poultry, canned foods, pasteurization): The time/temperature exposure during initial heat processing or cooking was inadequate to kill the pathogen under investigation. 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. Note: Citation of S1 does not include inactivation of preformed heat-stable toxins or destruction of bacterial spores during cooking. See Proliferation Factors such as P6, P7 or P8 as possible appropriate citations under this circumstance
S2	**Insufficient time and/or temperature during reheating (e.g. sauces, roasts):** The time/temperature exposure during reheating or heat processing of a previously cooked or heated food (which has often been cooled, frequently, overnight) was inadequate to kill the pathogens. This does not include inactivation of preformed heat-stable toxins. Citation of S2 does not include inactivation of preformed heat-stable toxins. See Proliferation Factors such as P6, P7 or P8 as possible appropriate citations under this circumstance.
S3	**Insufficient time and/or temperature control during freezing:** 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. Example: 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. 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.
S4	**Insufficient or improper use of chemical processes designed for pathogen destruction:** 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. 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:** A form of survival that does not fit into the above categories. Examples include failures of other processes (such as subjecting foods to irradiation, high pressure, drying conditions) that permit pathogens to survive.