

1. DISEASE REPORTING

A. Purpose of Reporting and Surveillance

1. To prevent transmission from infected persons.
2. To correct food-preparation practices that allow contamination with foodborne disease (FBD) agents.
3. To quickly remove a contaminated food product from the commercial market and limit the spread of an outbreak.
4. To expand current understanding of the transmission, pathogenesis and community impact of illness caused by FBD pathogens.
5. To identify new FBD agents, hazards or gaps in the food safety system.

B. Legal Reporting Requirements

1. Health care providers and Health care facilities: outbreaks and suspected outbreaks *immediately* notifiable to **local health jurisdiction**
2. Laboratories: No requirements for reporting foodborne disease; see disease-specific reporting requirements
3. Local health jurisdictions: **Immediately notifiable to the Washington State Department of Health (DOH) Office of Communicable Disease Epidemiology (CDE)**

C. Local Health Jurisdiction Investigation Responsibilities

1. **Immediately notify CDE when an outbreak is suspected.** DOH epidemiologists and food safety specialists are available to assist local health jurisdictions with FBD outbreak investigations. CDE epidemiologists are responsible for coordinating the investigation of multi-county and multi-state FBD outbreaks involving Washington residents.
2. Facilitate the transport of specimens to Public Health Laboratories to confirm an etiologic agent.
3. Perform epidemiologic and environmental investigations for FBD outbreaks.
4. Implement public health measures to prevent further spread.
5. Report FBD outbreak investigation summaries to CDE using the following forms:
 - [Foodborne Outbreak Reporting Form](#). This combines a DOH-specific cover sheet with the Centers for Disease Control and Prevention (CDC) National Outbreak Reporting System (NORS) Form
 - Additional guidance on NORS form available at <https://www.cdc.gov/nors/forms.html>
 - DOH Environmental Assessment Forms [Set 1](#) and [Set 2](#)

2. THE EPIDEMIOLOGY OF FOODBORNE DISEASES

A. Etiologic Agents, Descriptions of Illness and Incubation Periods

Etiologic agents of foodborne disease (FBD) can be grouped into 5 general categories:

1. **Bacterial toxins** (e.g., *Bacillus cereus* emetic and diarrheal toxins, *Clostridium perfringens* toxin, *Staphylococcus aureus* toxin, *Clostridium botulinum* toxin)
2. **Bacterial infections** (e.g., *Shigella*, *Salmonella*, Shiga toxin-producing *E. coli*, *Campylobacter jejuni*, *Listeria monocytogenes*, *Yersinia enterocolita*, *Vibrio*)
3. **Viruses** (e.g., Norovirus, hepatitis A virus)
4. **Parasites** (e.g., *Cryptosporidium*, *Cyclospora cayetanensis*, *Giardia*, *Trichinella*)
5. **Noninfectious agents** (e.g., metals, scombroid, mushroom and shellfish toxins)

FBD most commonly manifests with abdominal cramps, vomiting, and/or diarrhea. However, for some agents, FBD can present with neurologic symptoms (e.g., botulism, paralytic shellfish poisoning). Listeriosis can result in meningitis in older persons as well as fetal loss during pregnancy.

For a chart of common foodborne disease agents, descriptions of associated symptoms and incubation periods, see

<https://www.doh.wa.gov/Portals/1/Documents/5100/foodchart.pdf>

Additional information regarding foodborne illness agents can be found in: [Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Health Care Professionals](#).

B. Foodborne Disease in Washington State

During recent years, DOH has received approximately 30 to 50 reports of FBD outbreaks per year, involving approximately 300 to 700 ill persons per year. Studies suggest the true burden of FBD is many times higher. Agents more commonly causing outbreaks in Washington include norovirus, *Salmonella*, Shiga toxin-producing *E. coli* (STEC), and bacterial toxins. During most years, viral agents such as norovirus cause the largest number of FBD outbreaks and the largest outbreaks.

C. Reservoirs

Humans are the reservoir of hepatitis A virus, norovirus, *Shigella*, *Salmonella* Typhi, *Staphylococcus aureus*, and toxigenic *Vibrio cholera*.

Animals are the primary reservoirs of *Brucella*, *Campylobacter jejuni*, *Cryptosporidium parvum*, Shiga toxin-producing *Escherichia coli*, *Giardia*, *Salmonella* (non-Typhi), *Trichinella spiralis*, and *Yersinia enterocolitica*.

Vibrio are organisms that occur naturally in coastal waters. Shellfish can concentrate these organisms while filter feeding.

Bacillus cereus, *Clostridium*, heavy metals, and *Listeria monocytogenes* are found in the environment.

D. Modes of Transmission

By definition, FBD agents are transmitted through food, although many of these agents can be transmitted through other routes, such as water, animal contact, or directly person-to-person. Food items can become contaminated with FBD agents in the following ways:

1. Food items contaminated from nature

Raw contaminated food items that can be made safe by sufficient cooking include improperly canned products containing heat-labile botulinum toxin, foods with bacterial contamination, and animal-derived foods containing parasites. Examples include raw milk or milk products contaminated with *Brucella*, *Campylobacter*, *Listeria monocytogenes*, *Salmonella* or *Cryptosporidium parvum*; eggs or poultry contaminated with *Salmonella* or *Campylobacter* species; ground beef or wild game contaminated with *E. coli* O157; pork contaminated with *Yersinia enterocolitica*; and bivalve shellfish contaminated with *Vibrio parahaemolyticus*. Wild game meat can contain *Trichinella spiralis*, a parasitic roundworm. FBD caused by toxins within fish or shellfish include ciguatera, scombroid, and paralytic shellfish poisoning. These toxins are heat-stable and, as a result, these FBDs cannot be prevented by cooking contaminated fish or shellfish.

2. Food items contaminated by an ill food handler

Ill food handlers can contaminate food through their feces (on unwashed hands), vomitus or infected lesions. FBD outbreaks due to *Shigella*, hepatitis A, and norovirus are generally caused by contamination of uncooked or cooled food by an infected food handler. FBD outbreaks of hepatitis A and norovirus infection have been associated with consumption of raw oysters contaminated with human sewage before harvest or less commonly during processing by ill food handlers. *Staphylococcus aureus* introduced into food from a food handler's infected eye, skin, or nasopharynx can multiply at room temperature and produce a heat-stable toxin not destroyed by subsequent cooking.

3. Food items cross-contaminated by a contaminated food or the environment

Bacteria from animal-derived foods (e.g. beef and eggs) can cross-contaminate raw foods through cooking utensils, the hands of food workers, unclean food preparation surfaces, or improper storage. Contaminated water, dirt or sewage can introduce a number of agents into previously safe food. *Clostridium perfringens* and *Bacillus cereus* are found in the environment and may occur in grains or spices. Their spores are not inactivated by routine cooking. Outbreaks caused by these bacteria generally result from holding cooked food at temperatures that allow the bacteria to proliferate (between 45°–140°F, usually).

4. Food items intentionally contaminated

FBD agents can be intentionally added to foods to cause illness.

E. Periods of Communicability

Illness caused by preformed toxins (e.g., *Bacillus cereus*, *Staphylococcus aureus*, botulinum toxin) are not communicable. The communicable period varies for those infected with bacteria, viruses or parasites. See agent specific guidelines at:

<http://www.doh.wa.gov/PublicHealthandHealthcareProviders/NotifiableConditions/ListofNotifiableConditions.aspx>.

F. Treatment

Though treatment varies with the etiologic agent, most FBD requires only adequate hydration. Antibiotics may be appropriate for some agents. Botulism calls for urgent administration of antitoxin and close observation, generally in an intensive care unit.

Treatment recommendations for specific FBD agents can be found in: [Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Health Care Professionals](#).

G. Susceptibility/Immunity

Most people are susceptible to these agents. Infants and persons with lowered gastric acidity may be infected with lower inocula. Infants, the elderly, and immunosuppressed persons are more likely to suffer serious illness from selected agents. Pregnant women and the elderly are more likely to have severe illness and other complications from listeriosis. Hepatitis A is vaccine preventable.

3. FOODBORNE DISEASE OUTBREAK DEFINITIONS

A FBD **outbreak** is defined as an incident in which 1) two or more persons experience a similar illness after exposure to the same food source and 2) epidemiologic evidence implicates food as the likely source of the illness. (See [Appendix A](#) for more detailed definitions).

Outbreaks of FBD may result from various types of exposure including a point source (e.g., a particular event or food establishment), the widespread distribution of a perishable commodity, or a persistent contamination of a shelf-stable product.

4. DIAGNOSIS AND LABORATORY SERVICES

A. Laboratory Diagnosis

FBD outbreaks may or may not be laboratory confirmed. In general, confirming the etiologic agent in an outbreak requires detecting the agent in clinical specimens from at least 2 ill persons, or in implicated food. Guidelines for confirming the etiologic agent of a FBD outbreak are available in [Appendix B](#).

B. Tests Available at the Washington State Public Health Laboratories (PHL)

PHL has the capability to test stool specimens for many foodborne bacterial and parasitic pathogens and norovirus. PHL does not test clinical specimens for hepatitis A but this test is widely available in commercial labs.

PHL also has the capability to test food specimens for many bacterial pathogens, when indicated in the context of an outbreak investigation. PHL does not perform testing of food specimens for norovirus.

When submitting commercial food specimens, keep the food item in the original package and include all available documentation regarding the purchase of the item including receipts. Consult with CDE prior to submitting clinical or food specimens.

C. Specimen Collection

For additional information regarding testing clinical and food specimens at PHL, and for instruction regarding collecting and shipping clinical and food specimens, see [Foodborne Disease and the Public Health Labs: A Foodborne Pathogen Quick Reference Guide for Food Sanitarians](#).

5. ROUTINE INVESTIGATION and CONTROLLING FURTHER SPREAD

Outbreaks can be detected through Notifiable Conditions reporting, bacterial isolate sub-typing in the laboratory, consumer complaints, and syndromic surveillance systems. Even when resources are severely limited, local health jurisdictions should investigate outbreaks and suspected outbreaks that meet the following criteria:

- Illness is severe (e.g., hospitalization or death in 1 or more people, marine neurotoxin, mushroom poisoning, hepatitis)
- Illness is due to a confirmed or suspected bacterial source (e.g., bloody diarrhea, toxin)
- Outbreak is large (involves ≥ 10 ill people) or ongoing
- Illness is associated with shellfish from a commercial source or growing area
- Exposures have occurred in a setting with a vulnerable population
- Illness is suspected to be associated with a commercially-distributed food

As resources permit, local health jurisdiction should investigate other situations in which illness is associated with a common source reported by ≥ 2 unrelated households/parties.

Steps in outbreak investigation generally include the following:

A. Systematically collect information from cases to characterize the outbreak.

The [DOH Foodborne Illness Case Investigation Worksheet](#) can assist with collecting preliminary information:

1. Demographics, including name, address, telephone number, age, sex, and other relevant factors such as occupation, residence, classroom, unit/wing/ward, cell block, etc.
2. Symptoms, including vomiting, diarrhea, bloody diarrhea, fever, abdominal cramps, muscle aches, as well as hospitalization status and medical care received.
3. Date and time of symptom onset and how long symptoms lasted (illness duration).
4. Shared meals and food and drink consumption history for a period of at least 72 hours before illness onset. Note that some agents have longer incubation periods thus require collection of longer period of food history.
5. Names, addresses, phone numbers, and other locating information for anyone else who might be involved in the outbreak, both people who are sick and people who are not, and the name of the coordinator of a group activity, if applicable.

B. Attempt to identify additional cases. Methods might include calling others potentially exposed to the suspected source (e.g. event attendees or customers who purchased the same item), sending provider alerts, requesting specimens from laboratories, or releasing a media alert.

C. Confirm the existence of an outbreak. Local health jurisdictions should consider a number of questions, including the following: [Note: These questions provide guidance and are not strict criteria.]

1. Are there persons from different households with illness following the ingestion of the same food or meal or who visited the same commercial establishment?
2. Are illness signs and symptoms, along with the incubation period and symptom duration, consistent with an illness resulting from the reported exposure?
3. Are all the illnesses similar and consistent with a FBD agent?
4. Is the number of illnesses more than what would be expected in this group of people and in the population as a whole?
5. Are there reports of potentially associated cases from related sources?
6. Are there common exposures other than food (e.g., personal or occupational contact) that could explain transmission?
7. Does the demographic information (age, ethnicity, etc.) suggest a common source?

D. Formulate a hypothesis about the illness agent and arrange for appropriate laboratory testing, if indicated.

1. Refer ill persons for medical evaluation and testing if symptoms are severe, if bloody diarrhea is reported, or if the person is vulnerable to complications due to age or disability.
2. Collect fresh specimens for laboratory testing as soon as possible after onset of illness (See [Section 4C](#) for additional details regarding specimen collection.)
3. Collect specimens from as many people as possible. The criteria for confirming that an outbreak was caused by a specific agent usually depend on isolating the agent from at least two people involved in the outbreak.
4. In general, clinical specimens from food handlers should only be collected when they have had an illness compatible with that of cases involved in the outbreak (to ensure that they get appropriate treatment and their disease has resolved); or when humans are the only reservoir for the etiologic agent and it is necessary to identify the source of a confirmed infection (for example, *Salmonella* Typhi). Food handlers often eat at their work site and may be ill simultaneously with patrons.

E. Hold food specimens for possible testing.

If people have specimens of suspected food, ask that they be stored cold (not frozen) at home in containers that will resist breakage and contain spillage (or offer to store them cold at the local health jurisdiction). Ask that the original wrapper and purchase receipts be saved. Tell them that their food specimens may not be needed for microbiologic testing. For more information regarding testing food specimens, see [Section 4](#).

F. Develop a preliminary case definition that includes time, place, and person.

An example of a case definition: Diarrhea with abrupt onset between December 25 and December 26, 2012 (*time*) in any person at least 5 years of age (*person*) who ate supper at Church A on December 25, 2012 (*place*).

G. Implement an environmental field investigation based on the epidemiologic case data.

The goals of the joint epidemiologic and environmental outbreak investigation are to identify the infectious agent, the mode of transmission, the food vehicle, the source of the contamination and the contributing factors. If the suspected source is a local restaurant or other commercial establishment, conduct a process-focused inspection using the DOH Environmental Assessment Forms [Set 1](#) and [Set 2](#).

Consider the likely infectious agent based on symptoms and incubation period. Consider likely modes of transmission for that agent to focus the inspection (see [Section 2D](#)). For example, a norovirus outbreak is likely due to an ill food handler with inadequate hand hygiene. In contrast, a *Clostridium perfringens* outbreak is likely to result from food held at inappropriate temperatures. As appropriate, obtain the following additional information from both managers and staff:

1. What are the usual food-handling practices? How long is food prepared in advance? Is food allowed to sit unrefrigerated? For how long?
2. Were there any unusual circumstances or practices operative just before the outbreak began? Power outages? Water back-ups? Other equipment failures?
3. Were food handlers or their family members ill during the incubation period of the suspect FBD agent? When did they become ill? With which foods do they work? Do any food workers have cuts or sores on uncovered skin?
4. Do the food workers eat the foods they prepare? (Most ill food workers are victims rather than sources of FBD agents).

H. Implement immediate control measures based on the FBD agent, the vehicles for this agent and food-handling practices that permitted or facilitated transmission.

Depending on circumstances, immediate control measures may include food handling recommendations to restaurant workers, excluding or restricting a particular worker, closing a restaurant, disposing of contaminated food (after specimens have been collected), or issuing a press release to advise citizens who may develop symptoms.

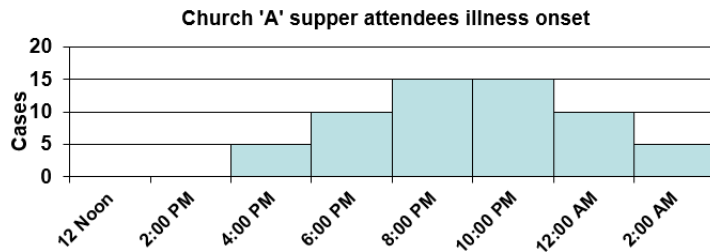
I. Consider testing hypotheses with an epidemiologic study. (i.e. case control or cohort)

1. Determine if initial interviews and the number of affected persons will support an epidemiologic study that compares groups of ill and well persons.
2. Get as complete a list as possible of all the people who attended the same function, ate at the same restaurant, etc.; lists can be obtained from an event organizer, from credit card receipts or from reservation lists.
3. Obtain a menu from the restaurant or other list of foods served at the event.
4. Develop a questionnaire to systematically collect information on symptoms and exposures.
5. Administer the questionnaire to as many people as possible, both sick and well, as soon as possible after the first cases are reported. It is important to remember that the longer you wait, the less reliable these data are.
6. After finalizing a case definition, analyze the data to obtain the following:

Demographic profile: the number of cases by age group and sex.

Symptom profile: the percentage of cases with vomiting, diarrhea, bloody diarrhea, fever, abdominal cramps, muscle aches, and any other symptoms.

Epidemic curve: the number of cases by time of onset of symptoms.



Event attack rate: the number of cases divided by the total number of people exposed. Event attack rate can only be calculated if the total number of people attending is known.

Median incubation period: the time it takes 50% of the cases to get sick after exposure to the FBD agent. The median incubation period can only be calculated if the date and time of exposure is known.

Food-specific attack rate: the percentage of people who became ill after eating a specific food (table 1, column 4).

Relative risks: the percentage of people who became ill after eating a certain food, divided by the percentage of people who became ill after not eating the same food (table 1, column 8).

P value: The probability that the elevated relative risk is due only to chance. $P < 0.05$ means that chance is a very unlikely explanation for the difference in relative risks (less than 5 times out of a 100), and is the conventional cut-off to say the food is "statistically significantly associated with illness". However P value is dependent on the number of persons included in the analysis and must be interpreted in that context.

Table 1 is an example of data summary from an event- based cohort study.

Table 1. Food-specific attack rates, relative risks and P values, Church Supper attendees								
Food Item	DID EAT the Specific Food			DID NOT EAT the Specific Food			Statistics	
	Number Sick	Number Well	Attack Rate	Number Sick	Number Well	Attack Rate	Relative Risk	P value
Turkey	55	45	55%	5	95	5%	11	<.001
Gravy	40	60	40%	20	80	20%	2	.004
Mashed potatoes	42	58	42%	18	82	18%	2.3	.005
Ham	35	65	35%	25	75	25%	1.4	0.1
Pears	30	70	3%	30	70	3%	1	1
Formulas	A	B	$A / (A+B) = X\%$	C	D	$C / (C+D) = Y\%$	X% / Y%	*

* Statistical programs, such as EpiInfo, SAS or SPSS are commonly used to calculate P values.

Epi Info is a CDC-developed statistical software package available free of charge at:

<https://www.cdc.gov/epiinfo/>.

J. Implement and evaluate further control measures

Control measures specified in Section H may need to be initiated or expanded and may also include food safety training, or notifying state or federal food regulatory agencies. In addition, there will likely be follow-up verification that food worker exclusion or changes in food preparation practices have been met.

Patients and contacts should be instructed in good hand washing and food-handling practices. Persons with vomiting or diarrhea should not handle or prepare food to be eaten by others. More specific follow-up of cases and contacts varies with the etiologic agent. Please refer to disease-specific [Surveillance and Reporting Guidelines](#) for guidance on specific diseases and the [Washington State Food Code](#).

K. Report findings to DOH

Report FBD outbreak investigation summaries to CDE using the following forms:

- [Foodborne Outbreak Reporting Form](#). This combines a DOH-specific cover sheet with the CDC National Outbreak Reporting (NORS) Form
 - Additional guidance on NORS form available at <https://www.cdc.gov/nors/forms.html>
- DOH Environmental Assessment Forms [Set 1](#) and [Set 2](#)

7. ROUTINE PREVENTION

For general food safety tips see:

<https://www.doh.wa.gov/YouandYourFamily/FoodSafety/Tips.aspx>

<https://foodsafety.gov/>

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UPDATES

January 2013: Section 5 was updated to include information on prioritizing investigations of outbreaks and suspected outbreaks.

June 2017: Sections 1 and 6 were updated to reflect adoption of CDC's NORS form for reporting foodborne outbreaks, in place of the DOH form.

June 2019: Foodborne Outbreak Appendix B document added at the end of this guideline.

December 2022: For 2023 WAC revision combined provider and facility reporting requirement, updated laboratory submission (Section 1B)

APPENDIX A: Foodborne Disease Outbreak Definitions

A foodborne disease (FBD) outbreak is defined as an incident in which 1) two or more persons experience a similar illness after exposure to the same food source and 2) epidemiologic evidence implicates the food as the likely source of the illness.

Laboratory-confirmed: An outbreak of FBD with laboratory evidence confirming the outbreak etiology.

Probable: An outbreak of FBD with observational evidence and contributing factors without laboratory evidence.

Suspected: A group of cases linked by time or place (also known as a cluster) but without evidence linking illnesses to a common food. Suspected outbreaks of FBD may lead to public health activities, including heightened oversight of a facility, but do not require submission of a summary report to DOH.

Types of epidemiologic evidence

Types of evidence gained by epidemiologic and environmental investigation

- Illnesses are consistent with exposure to a foodborne agent AND illness onsets are consistent with exposure to a common food AND exposure cannot be explained by another transmission route (e.g. person-to-person or zoonotic) or other exposures.
- Contributing factors are identified that are consistent with the epidemiological and/or laboratory evidence
- Analytic epidemiological study with statistically significant association between illness and exposure to a common food

Types of laboratory evidence

- Detection of an agent in human cases with descriptive evidence of a common food exposure
- Detection of an agent in a food vehicle and illnesses compatible with the agent in outbreak cases
- Detection of an agent in human cases and in a food vehicle

Additional Definitions

Case-patient (abbreviated as Case): A person in the population or study group identified as having the particular disease or condition under investigation.

Agent: A pathogen or toxin considered to be the cause of the outbreak of foodborne illness.

Food Vehicle: Food that is contaminated by an agent. The vehicle provides the means for an agent to come into contact with a susceptible individual.

Common Food: Documentation that cases consumed the same food or meal at an identified food facility or group gathering; or cases consumed a food product distributed from an identified common source.

Contributing Factor: A fault or circumstance that singly or in combination led to the outbreak of foodborne disease. Contributing factors may include food handling practices which lead to: the contamination of a food; and/or the proliferation, amplification and/or survival of an agent.

APPENDIX B: CRITERIA FOR CONFIRMATION OF FOODBORNE OUTBREAKS

The Centers for Disease Control and Prevention has established criteria for confirming the etiology when a foodborne outbreak has been identified. These criteria can be found in the following table and at https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/confirming_diagnosis.html

Table 2: Guidelines for Confirmation of Foodborne Disease Outbreaks

*Tests Available at WA State Public Health Laboratories are indicated by an asterisk

Etiologic agent	Confirmation Criteria
Bacterial	
1. <i>Bacillus cereus</i>	
a. Vomiting toxin	*Isolation of organism from stool of two or more ill persons and not from stool of control patients <u>OR</u> *Isolation of 10 ⁵ organisms/g from epidemiologically implicated food, provided specimen is properly handled
b. Diarrheal toxin	*Isolation of organism from stool of two or more ill persons and not from stool of control patients <u>OR</u> *Isolation of 10 ⁵ organisms/g from epidemiologically implicated food, provided specimen is properly handled
2. <i>Brucella</i>	
	*Two or more ill persons and isolation of organism in culture of blood or bone marrow <u>OR</u> Greater than fourfold increase in standard agglutination titer (SAT) over several wks, or single SAT 1:160 in person who has compatible clinical symptoms and history of exposure
3. <i>Campylobacter jejuni/coli</i>	
	*Isolation of organism from clinical specimens from two or more ill persons <u>OR</u> Isolation of organism from epidemiologically implicated food
4. <i>Clostridium botulinum</i>	
	*Detection of botulinum toxin in serum, stool, gastric contents, or implicated food <u>OR</u> *Isolation of organism from stool or intestine
5. <i>Clostridium perfringens</i>	
	*Isolation of 10 ⁶ organisms/g from stool of two or more ill persons, provided specimens are properly handled. <u>OR</u> Demonstration of enterotoxin in the stool of two or more ill persons <u>OR</u> *Isolation of 10 ⁵ organisms/g from epidemiologically implicated food, provided specimen is properly handled
6. <i>Escherichia coli</i>	
a. Enterohemorrhagic (<i>E. coli</i> O157:H7 and others)	*Isolation of <i>E. coli</i> O157:H7 or other Shiga-like toxin-producing <i>E. coli</i> from clinical specimen from two or more ill persons <u>OR</u> *Isolation of <i>E. coli</i> O157:H7 or other Shiga-like toxin-producing <i>E. coli</i> from epidemiologically implicated food

Etiologic agent	Confirmation Criteria
b. Enterotoxigenic (ETEC)	Isolation of organism of same serotype, demonstrated to produce heat-stable (ST) and/or heat-labile (LT) enterotoxin, from stool of two or more ill persons
c. Enteropathogenic (EPEC)	Isolation of organism of same enteropathogenic serotype from stool of two or more ill persons
d. Enteroinvasive (EIEC)	Isolation of same enteroinvasive serotype from stool of two or more ill persons
7. <i>Listeria monocytogenes</i>	
a. Invasive disease	Isolation of organism from normally sterile site
b. Diarrheal disease	Isolation of organism of same serotype from stool of two or more ill persons exposed to food that is epidemiologically implicated or from which organism of same serotype has been isolated
8. Nontyphoidal <i>Salmonella</i>	
	*Isolation of organism of same serotype from clinical specimens from two or more ill persons <u>OR</u>
	*Isolation of organism from epidemiologically implicated food
9. <i>Salmonella</i> Typhi	
	*Isolation of organism from clinical specimens from two or more ill persons <u>OR</u>
	*Isolation of organism from epidemiologically implicated food
10. <i>Shigella</i> spp.	
	*Isolation of organism of same serotype from clinical specimens from two or more ill persons <u>OR</u>
	*Isolation of organism from epidemiologically implicated food
11. <i>Staphylococcus aureus</i>	
	Isolation of organism of same phage type from stool or vomitus of two or more ill persons <u>OR</u>
	*Detection of enterotoxin in epidemiologically implicated food <u>OR</u>
	*Isolation of 10 ⁵ organisms/g from epidemiologically implicated food, provided specimen is properly handled
12. <i>Streptococcus</i>, group A	
	Isolation of organism of same M- or T-type from throats of two or more ill persons <u>OR</u>
	Isolation of organism of same M- or T-type from epidemiologically implicated food
13. <i>Vibrio cholerae</i>	
a. O1 or O139	
	*Isolation of toxigenic organism from stool or vomitus of two or more ill persons <u>OR</u>
	Significant rise in vibriocidal, bacterial-agglutinating, or antitoxin antibodies in acute- and early convalescent-phase sera among persons not recently immunized <u>OR</u>
	*Isolation of toxigenic organism from epidemiologically implicated food
b. non-O1 and non-O139	
	*Isolation of organism of same serotype from stool of two or more ill persons

Etiologic agent	Confirmation Criteria
14. <i>Vibrio parahaemolyticus</i>	Isolation of Kanagawa-positive organism from stool of two or more ill persons <u>OR</u> Isolation of 10 ⁵ Kanagawa-positive organisms/g from epidemiologically implicated food, provided specimen is properly handled
15. <i>Yersinia enterocolitica</i>	*Isolation of organism from clinical specimen from two or more ill persons <u>OR</u> Isolation of pathogenic strain of organism from epidemiologically implicated food
Chemicals	
1. Marine toxins	
a. Ciguatoxin	Demonstration of ciguatoxin in epidemiologically implicated fish <u>OR</u> Clinical syndrome among persons who have eaten a type of fish previously associated with ciguatera fish poisoning (e.g., snapper, grouper, or barracuda)
b. Scombroid toxin (histamine)	Demonstration of histamine in epidemiologically implicated fish <u>OR</u> Clinical syndrome among persons who have eaten a type of fish previously associated with histamine fish poisoning (e.g., mahi-mahi or fish of order Scomboidei)
c. Paralytic or neurotoxic shellfish poison	*Detection of toxin in epidemiologically implicated food <u>OR</u> Detection of large numbers of shellfish-poisoning-associated species of dinoflagellates in water from which epidemiologically implicated mollusks are gathered
d. Puffer fish, tetrodotoxin	Demonstration of tetrodotoxin in epidemiologically implicated fish <u>OR</u> Clinical syndrome among persons who have eaten puffer fish
2. Heavy metals (Antimony, Cadmium, Copper, Iron, Tin, Zinc)	*Demonstration of high concentration of metal in epidemiologically implicated food
3. Monosodium glutamate (MSG)	Clinical syndrome among persons who have eaten food containing MSG (e.g., usually 1.5 g MSG)
4. Mushroom toxins	
a. Shorter-acting toxins (Muscimol, Muscarine, Psilocybin, <i>Coprinus artrementaris</i> , Ibotenic acid)	Clinical syndrome among persons who have eaten mushroom identified as toxic type <u>OR</u> Demonstration of toxin in epidemiologically implicated mushroom or food containing mushroom
b. Longer-acting toxins (e.g., <i>Amanita</i> spp.)	Clinical syndrome among persons who have eaten mushroom identified as toxic type <u>OR</u> Demonstration of toxin in epidemiologically implicated mushroom or food containing mushrooms

Etiologic agent	Confirmation Criteria
Parasitic	
1. <i>Cryptosporidium</i> spp.	*Demonstration of oocysts in stool or in small-bowel biopsy of two or more ill persons <u>OR</u> Demonstration of organism in epidemiologically implicated food
2. <i>Cyclospora cayetanensis</i>	*Demonstration of the parasite by microscopy or molecular methods in stool or in intestinal aspirate or biopsy specimens from two or more ill persons <u>OR</u> Demonstration of the parasite in epidemiologically implicated food
3. <i>Giardia intestinalis</i>	*Demonstration of the parasite in stool or small-bowel biopsy specimen of two or more ill persons
4. <i>Trichinella</i> spp.	Two or more ill persons and positive serologic test or demonstration of larvae in muscle biopsy <u>OR</u> *Demonstration of larvae in epidemiologically implicated meat
Viral	
1. Hepatitis A	Detection of immunoglobulin M antibody to hepatitis A virus (IgM anti-HAV) in serum from two or more persons who consumed epidemiologically implicated food
2. Norovirus (NoV)	*Detection of viral RNA in at least two bulk stool or vomitus specimens by real-time or conventional reverse transcriptase-polymerase chain reaction (RT-PCR) <u>OR</u> Visualization of viruses (NoV) with characteristic morphology by electron microscopy in at least two or more bulk stool or vomitus specimens <u>OR</u> Two or more stools positive by commercial enzyme immunoassay (EIA)
3. Astrovirus	Detection of viral RNA in at least two bulk stool or vomitus specimens by real-time or conventional reverse transcriptase-polymerase chain reaction (RT-PCR) <u>OR</u> Visualization of viruses (NoV) with characteristic morphology by electron microscopy in at least two or more bulk stool or vomitus specimens <u>OR</u> Two or more stools positive by commercial enzyme immunoassay (EIA)

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