

Guidelines for Completing the California Department of Public Health Foodborne Disease Outbreak Report (CDPH 8567)

(Adapted from NORS 52.13 Guidance Document for NORS Users
reporting foodborne, person-to-person, and animal contact)

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Please use the Foodborne Disease Outbreak Report (CDPH 8567) to report:

- Two or more cases of similar illness from separate households resulting from the ingestion of a common food, OR
- Two or more cases of illness resulting from ingestion of food confirmed or suspected to be contaminated with botulism, marine toxins, or other chemicals.

LOCAL ID NUMBER

In the top right corner of the form, enter your local health department's ID number for the outbreak. Also, indicate if this is a preliminary or final report. If preliminary and final reports are both submitted, please use the same local ID number.

SECTION 1: FOODHANDLER

Was foodhandler implicated as the source of contamination? – Indicate if a foodhandler was implicated as the source of the outbreak.

If **Yes**, specify what evidence was used to support this conclusion. The choice of “prior experience makes this the likely source” is provided for situations when conclusive laboratory and epidemiologic evidence is absent, but other factors may prompt the investigator to suspect the foodhandler(s). If a foodhandler is implicated in the absence of laboratory and epidemiologic evidence, please explain in the *Remarks and Conclusions* section (Section 24).

Note: The purpose of this report is to capture information about the actual outbreak itself. If a foodhandler was implicated as the source of contamination, do NOT include the foodhandler's information in any sections of this report that ask about case information; that is, do NOT include the foodhandler in the case count, demographic data, any date fields, etc. Additional information about an implicated foodhandler may be included in the *Remarks and Conclusions* section (Section 24). If any foodhandlers are involved in the outbreak as cases (not the source), they should be included in case information.

SECTION 2: INVESTIGATION METHODS

Investigation Methods – Select all methods that apply.

- **Interviews only of ill persons** – Select if only ill persons were interviewed.
- **Case-control study** – This is an epidemiological study to evaluate the relationship between an exposure (e.g., eating contaminated food) and a particular outcome (e.g., illness). There are two categories of study participants, people who have the outcome of interest (cases) and people who do not have the outcome of interest (controls). Select this method if both ill persons and non-ill persons who may have had common exposures were interviewed, and this investigation method was used. Please attach any reports or tables associated with the case-control study.
- **Cohort study** – This is an epidemiological study used to assess outcomes (e.g., the development of gastrointestinal illness) in a group/cohort of people. Study participants are observed over time or counted to determine how many people experience the outcome of interest, and when the outcome occurred. Members in a cohort are defined according to their exposure profile (e.g., an exposed group and an unexposed group). In outbreak investigations, a cohort is frequently defined by membership in an organization (e.g., a boy scout troop attending a weeklong camp). Select this method if this investigation method was used. Please attach any reports or tables associated with the cohort study.

- **Food preparation review** – Select if a review of the preparation practices associated with the suspect food was conducted.
- **Investigation at factory or production plant** – Select if a factory or production plant was investigated (e.g., poultry processing plant).
- **Investigation at original source** – Select if the original source of implicated food was investigated (e.g., poultry farm, marine estuary, etc.).
- **Food product traceback** – Select if a traceback of the implicated food was conducted.
- **Environment or food sample testing** – Select if samples were taken from the environment or food for testing.
- **Other** – Select if investigation method is not listed above, and provide additional investigation methods in the *Comments* field.

Comments – Please enter any additional information relevant to the investigation methods.

SECTION 3: DATES (PRIMARY CASES ONLY)

The following dates refer only to primary cases; exclude any foodhandlers implicated as source of outbreak and any secondary cases.

Date First Case Became Ill (required field) – Indicate date first case became ill.

Date Last Case Became Ill – Indicate date last case became ill. If unknown, leave this field blank.

Date of Initial Exposure – Indicate date when first known exposure took place among primary cases. If unknown, leave this field blank.

Date of Last Exposure – Indicate date last known exposure took place among primary cases. If unknown, leave this field blank.

Date LHD or State First Notified of This Outbreak – Enter date when LHD or State first learned about the outbreak (via telephone, e-mail, fax, etc.).

Time LHD or State First Notified of This Outbreak – If known, enter time when LHD or State first learned about the outbreak (via telephone, e-mail, fax, etc.).

Date Investigation Initiated – Enter date when investigation of outbreak was initiated.

Time Investigation Initiated – If known, enter time when investigation of outbreak was initiated.

SECTION 4: GEOGRAPHIC LOCATION

Reporting State (required field) – Indicate state reporting outbreak.

If Multiple States Involved – If multiple states involved in outbreak, select one option.

- **Exposure occurred in multiple states** – Indicate if outbreak resulted from exposure that occurred in multiple states. A multistate foodborne outbreak is defined as the occurrence of two or more cases of a similar illness resulting from **exposure to a common source**, where exposure occurred in **more than one state** (e.g., product from manufacturer X that was distributed to two or more states). States involved in a multistate outbreak will create one NORS-foodborne outbreak report for their state. Please note: An outbreak where the exposure occurred in multiple states and a common exposure was determined would be considered a multistate outbreak and the reports would be consolidated by someone at CDC. However, if the possible exposure occurred in multiple states but a common exposure was not identified (e.g., PFGE

cluster is reported and investigation does not yield a common food vehicle), the cluster would not be considered a multistate outbreak by CDC.

- **Exposure occurred in a single state, but cases resided in multiple states** – Indicate if exposure occurred in a single state, and ill persons were residents of multiple states. For example, residents from California, New York, and Florida (multiple states) attended an event (convention) in California (single state) and became ill from exposure at the event.

If Multiple States Involved, List Additional States – List other states involved in the outbreak.

Reporting Local Health Jurisdiction - Indicate local health jurisdiction reporting outbreak.

If Multiple Local Health Jurisdictions Involved – If multiple local health jurisdictions involved in outbreak, select one option.

- **Exposure occurred in multiple jurisdictions** – Indicate if outbreak resulted from exposure that occurred in multiple local health jurisdictions in California.
- **Exposure occurred in a single jurisdiction, but cases resided in multiple jurisdictions** – Indicate if exposure occurred in a single jurisdiction, and ill persons were residents of multiple local health jurisdictions. For example, residents from Los Angeles, Orange, and San Diego counties (multiple counties of California) attended an event in Los Angeles (single jurisdiction) and became ill from an exposure at the event.

If Multiple Local Health Jurisdictions Involved, List Additional Jurisdictions – List other local health jurisdictions involved in the outbreak.

Name of Facility Where Exposure Occurred – If outbreak was associated with only one facility, indicate name of facility if it is publicly available.

City/Town of Exposure – If outbreak was associated with only one facility, indicate city or town of facility.

SECTION 5: PRIMARY CASES (DO NOT INCLUDE IMPLICATED FOODHANDLERS IN CASE COUNTS)

This section refers only to primary cases; exclude any foodhandlers implicated as the source of outbreak. Any household contacts who became ill from person-to-person transmission would be secondary cases. Any cases that can be clearly defined as secondary cases should be detailed in *Secondary Cases* section (Section 9). For outbreaks where multiple modes of transmission or exposures are suspected but cannot be separated from one another, classify all cases as primary cases.

Case Definition – Provide the criteria used to define a case for the outbreak, including person, place, and time.

Example 1: Point Source Cluster

- Case Definition: Person who developed gastrointestinal illness within seven days of attending wedding reception at Hotel X on February 14, 2011.

Example 2: PFGE-Defined Cluster

- Case Definition: Person with: 1) *Salmonella* Typhimurium infection, 2) illness onset (or specimen collection date, if onset date unknown) on February 27 – July 1, 2012, and 3) isolate matching PFGE *Xba*I pattern JPXX01.2350.

Number of Primary Cases:

- **# Lab-confirmed Cases** – Indicate number of primary cases in which a specimen was collected, and a laboratory was able to confirm the pathogen(s) or agent(s) responsible for the illness. Marine toxin cases

that meet exposure and symptom confirmation guidelines should be included in this count. For foodborne outbreaks, the source case such as the foodhandler who was lab confirmed should not be included in this count.

- **# Probable Cases** – Indicate number of primary cases that are epidemiologically linked to a confirmed case or setting, but do not have laboratory confirmation (e.g., a specimen was not collected or submitted to a laboratory). For foodborne outbreaks, the source case such as the ill foodhandler should not be included in this count.
- **Estimated Total Primary III** – Indicate total number of all lab-confirmed and probable primary cases using the outbreak-specific definition. The estimated total primary ill should be **greater than or equal to** the sum of the lab-confirmed and probable primary cases.

Notes:

- An epidemiologically linked case is a case in which: a) the patient has had contact with one or more persons who either have/had the disease or have been exposed to a point source of infection (i.e., a single source of infection, such as an event leading to a foodborne-disease outbreak, to which all confirmed case-patients were exposed) and b) transmission of the agent by the usual modes of transmission is plausible.
- The # Lab-confirmed Cases and # Probable Cases fields are not required. If the # Lab-confirmed Cases versus # Probable Cases fields are not easily determined using the outbreak-specific case definition, leave those fields blank and enter the outbreak-specific case count as the # Estimated Total Primary III.

Example 1 – In an outbreak of salmonellosis, the State defines a confirmed case as “a person who ate at buffet restaurant X with an illness onset date on or after September 1, 2010”. The State reported 10 cases that met this case definition. Of these 10 cases, 2 cases were lab-confirmed salmonellosis. For NORS reporting purposes:

- # Lab-confirmed Primary Cases: 2 cases
- # Probable Primary cases: 8 cases
- # Estimated Total Primary III: 10 cases

Example 2 – In an outbreak of unknown etiology, 12 people reported becoming ill after consuming hamburgers at a banquet. Laboratory testing was inconclusive. For NORS reporting purposes:

- # Lab-confirmed Primary Cases: BLANK
- # Probable Primary Cases: 12 cases
- # Estimated Total Primary III: 12 cases

Death and Health Care Visits (required fields):

Please note: Death, Overnight Hospitalization, Emergency Room Visits, and Health Care Provider Visits are NOT mutually exclusive categories.

- **Death**
 - **# Cases Died** – Indicate number of deaths among primary cases that resulted from the outbreak. Please do not leave this field blank. If there were no deaths, please enter 0. If a case was hospitalized with an unrelated illness, became ill with the outbreak-related pathogen, and then died due to the outbreak pathogen, they should be included in this count. Neonatal deaths should be included in this count. Fetal loss should not be included in this count, but these should be noted in the *Remarks and Conclusions* section (Section 24).
 - **Total # Cases for Whom Information is Available** – Indicate the total number of primary cases for whom information on survival status is available.

- **Overnight Hospitalization**
 - **# Cases Hospitalized Overnight** – Indicate number of primary cases who were hospitalized overnight as a result of becoming ill during the outbreak.
 - **Total # Cases for Whom Information is Available** – Indicate the total number of primary cases for whom information on hospitalization status is available.
- **Emergency Room Visits**
 - **# Cases Visited Emergency Room** – Indicate number of primary cases who visited an emergency room or department as a result of becoming ill during the outbreak.
 - **Total # Cases for Whom Information is Available** – Indicate the total number of primary cases for whom information regarding emergency room or department visits is available.
- **Health Care Provider Visits**
 - **# Cases Visited Health Care Provider** – Indicate the total number of primary cases who visited any kind of **outpatient** health care provider, including primary care or specialty physicians, physician’s assistants, nurses, or other medical professionals, or urgent care facilities, as a result of becoming ill during the outbreak. Do not include ER visits or hospitalizations in this field.
 - **Total # Cases for Whom Information is Available** – Indicate the total number of primary cases for whom information on outpatient healthcare provider visits is available.

Sex – Indicate the approximate percentage of primary cases of each sex. Please be sure that percentages total to 100.

Age Group – Indicate the approximate percentage of primary cases in each age group. Please be sure that percentages total to 100.

SECTION 6: INCUBATION PERIOD (PRIMARY CASES ONLY)

This section refers only to primary cases; exclude any foodhandlers implicated as the source of outbreak and any secondary cases. The incubation period is the time between the implicated exposure and the clinical onset of illness for primary cases. For example, if cases ate contaminated beef on May 1 and episodes of diarrhea started May 5, the incubation period would be 4 days (May 1 – 5).

Is incubation period known? – Indicate if incubation periods for any primary cases are known.

- If **Yes**, indicate the total number of primary cases for whom information is available, and the shortest, median, and longest incubation periods. If sufficient data is not available to calculate a particular incubation period, leave that incubation period field blank. In addition, select the appropriate units (minutes, hours, or days). If information is only available for one case, then enter the same information for the shortest, median, and longest incubation periods.

SECTION 7: DURATION OF ILLNESS (AMONG RECOVERED PRIMARY CASES ONLY)

This section refers only to primary cases; exclude any foodhandlers implicated as the source of outbreak and any secondary cases. The duration of illness is the time from the onset of the earliest symptom to the end of final gastrointestinal symptom. For example, a case had episodes of diarrhea that started on March 4 and vomiting that started on March 5. The diarrhea ended on March 6, but vomiting continued until March 7, so the duration of illness would be 3 days (March 4 – 7).

Is duration of illness known? – Indicate if durations of illness for any primary cases are known.

If **Yes**, indicate the total number of primary cases for whom information is available, and the shortest, median, and longest durations of illness among those who have recovered. If sufficient data is not available to calculate a particular duration, leave that duration field blank. In addition, select the appropriate units (minutes, hours, or days). If information is only available for one case, then enter the same information for the shortest, median, and longest durations of illness.

SECTION 8: SIGNS OR SYMPTOMS (PRIMARY CASES ONLY)

This section refers only to primary cases; exclude any foodhandlers implicated as the source of outbreak and any secondary cases. Indicate the number of cases with each sign/symptom/outcome and the total number of cases for whom information about that specific sign/symptom/outcome is available. Please add any additional symptoms that affected a significant proportion of cases (see list of additional signs/symptoms on page 8 of report form).

Note: If a Shiga toxin-producing *Escherichia coli* (e.g., *E. coli* O157:H7) is the outbreak etiology, please enter available data for hemolytic uremic syndrome (HUS).

- If no cases were asked about HUS, enter 0 for ‘# Cases with Sign/Symptom’ and ‘Total Number of Cases for Whom Information is Available’
- If the number of cases who were asked about HUS is unknown, leave ‘Total Number of Cases for Whom Information is Available’ blank.

Example – Four cases of Shiga toxin-producing *E. coli* infections were all asked if they had HUS. One case reported HUS and three did not have HUS. For NORS reporting purposes:

- # Cases with Sign/Symptom: 1 case
- Total # of Cases for Whom Information is Available: 4 cases

SECTION 9: SECONDARY CASES

A secondary case is a person was not directly exposed to the implicated food in the initial outbreak but had another exposure that led to illness (most commonly, person-to-person contact with a primary case). Any household or close contacts who became ill from person-to-person transmission would be secondary cases.

Any cases that are ill via a clearly defined secondary mode of transmission or exposure context should be detailed in this section. For outbreaks where multiple modes of transmission or exposures are suspected but cannot be separated from one another, classify all cases as primary cases.

Number of Secondary Cases:

- **# Lab-confirmed Secondary Cases** – Indicate number of secondary cases in which a specimen was collected, and a laboratory was able to confirm the pathogen(s) or agent(s) responsible for the illness.
- **# Probable Secondary Cases** – Indicate number of secondary cases that are suspected of being associated with the implicated pathogen(s) or agent(s) but do not have laboratory confirmation (e.g., a specimen was not collected or submitted to a laboratory).
- **# Estimated Total Secondary Cases** – Indicate total number of all lab-confirmed and probable secondary cases.
- **# Total Cases (Primary + Secondary)** – Indicate total number of primary and secondary cases.

SECTION 10: TRACEBACK

A traceback is conducted by local, state, and/or federal authorities to determine the source of a food, as far back to its origin as possible.

Was traceback conducted? – Indicate if a traceback was attempted, regardless of its success.

If **Yes**, indicate if a source was identified. If a source was identified through traceback, specify details in *Traceback – Details* section (Section 11).

SECTION 11: TRACEBACK – DETAILS

For each source identified through traceback, provide the following information:

- **Source Name** – Indicate the name of the company or facility from which the contaminated food came (e.g., name of grocery store, farm, ranch, etc.) if made publicly available by regulatory agency and/or the company.
- **Source Type** – Indicate the type of facility from which the contaminated food came (e.g., poultry farm, tomato-processing plant, etc.).
- **Location of Source - State** – Indicate state (or if not in the United States, the area, province, or region) from which the contaminated food came.
- **Location of Source - Country** – Indicate country from which the contaminated food came.
- **Comments** – Indicate agency that conducted the traceback and any additional comment(s) pertaining to the information found in the traceback.

If more than two sources were identified, please provide the traceback details listed above for the other sources on additional sheets of paper.

SECTION 12: RECALL AND CONTROL MEASURES

Was any food product recalled? – Indicate if any foods involved in the outbreak were recalled.

If **Yes**, specify type of item recalled (e.g., eggs, peanut butter, ground beef, etc.). Information about the recall may be included in the *Recall Comments* field.

Recall Comments – Enter any additional information relevant to the recall such as brands, lot numbers, recall date, etc.

Other Control Measures – Besides recall, indicate any other control measures taken to prevent additional illnesses.

SECTION 13: ETIOLOGY (PRIMARY CASES ONLY)

Is etiology known or suspected? – Indicate if there is a confirmed or suspected etiology.

If **Yes** (there is a confirmed or suspected etiology), skip to *Etiology – Details* sections 14.1 and 14.2 to specify details of all confirmed and suspected etiologies.

If **No** (there is no confirmed or suspected etiology), indicate if patient specimens were collected. If patient specimens were collected, provide the following details:

- **How many patients had specimens collected and tested?** – Indicate the number of patients who had specimens collected and tested by a laboratory.
- **What were they tested for?** – Indicate whether the specimens were tested for bacteria, viruses, chemicals/toxins, and/or parasites. Check all that apply.

SECTIONS 14.1 AND 14.2: ETIOLOGY – DETAILS (PRIMARY CASES ONLY)

Name the bacterium, virus, chemical/toxin, or parasite. If available, include the species, serotype, and other characteristics such as phage type, virulence factors, and metabolic profile.

For each identified or suspected etiology, provide the following information:

- **Etiology** – Select the confirmed or suspected etiology from the list provided, or select “Other” and specify the etiology in the space provided. If more than one species/serotype of a single genus is involved in an outbreak (e.g., both *Salmonella* Enteritidis and *Salmonella* Javiana), enter each one as a separate etiology.
 - **If *Campylobacter*, *Shigella*, or *Vibrio***, indicate species in the *Other Characteristics* field.
 - **If *E. coli*/STEC**, select serotype from the list provided, or select “Other” and specify in the space provided.
 - **If *Salmonella***, select serotype from the list provided, or select “Other” and specify in the space provided.
- **Other characteristics** – List any other distinguishing characteristics (e.g., species, genotype, etc.) not already captured elsewhere on the form.
- **Confirmed outbreak etiology?** – Check “Yes” if the etiology listed is the confirmed etiology for the outbreak. Check “No” if etiology listed is suspected but not been lab confirmed.
Note: For most etiologic agents, CDC considers an outbreak to have a confirmed etiology if there are two or more lab-confirmed cases. However, because botulism, marine toxin, and other chemical outbreaks have such distinct clinical symptoms, a physician’s diagnosis is often sufficient and laboratory confirmation is not necessary to classify an outbreak as having a confirmed etiology. Therefore, for such outbreaks, CDC would consider the etiology confirmed if there are at least 2 cases (lab confirmed and/or probable) with signs and symptoms meeting the confirmation criteria. For such outbreaks, indicate ‘Yes’ for ‘Confirmed outbreak etiology?’; however, those cases should NOT be included as lab-confirmed cases unless a laboratory confirmed the etiologic agent. Please refer to CDC’s *Guide to Confirming a Diagnosis in Foodborne Disease* at:
http://www.cdc.gov/outbreaknet/references_resources/guide_confirming_diagnosis.html.
- **What was it detected in?** – Indicate whether the etiology listed was detected in: 1) patient specimen, 2) food specimen, 3) environmental specimen, and/or 4) foodhandler specimen. Check all specimens that apply. In outbreaks of botulism, marine toxins, and other chemicals, etiology may be based on clinical evidence only. In such outbreaks, please check box for “Clinical evidence only”.
- **# Lab-confirmed Cases** – Indicate how many primary cases were due to the listed etiology that were also confirmed by laboratory testing.

If more than two etiologies were identified, please provide the details listed above for the other etiologies on additional sheets of paper.

Note: For foodborne outbreaks suspected to be due to norovirus, please complete sections 13 and 14.1 as follows:

- In Section 13 (Etiology):
 - Check “Yes” for “Is etiology known or suspected?”
- In Section 14.1 (Etiology #1 – Details):
 - Check “Norovirus” for “Etiology 1” AND
 - Check “No” for “Confirmed outbreak etiology”

SECTION 15: ISOLATES

For bacterial pathogens, provide representative laboratory data for each distinct PFGE pattern, if available. For viral pathogens (norovirus and sapovirus), provide CaliciNet outbreak code, key, and genotype for each distinct strain identified in the outbreak, if available. If you do not have any isolates, enter “N/A” or “Unavailable” under “State or Local Lab ID” for Isolate 1.

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

If more than three distinct patterns were identified or more than three specimens were submitted for viral sequencing, please provide the details listed above for the other patterns on additional sheets of paper.

For information related to PulseNet, please visit: <http://www.cdc.gov/pulsenet/index.htm>.

SECTION 16: IMPLICATED FOODS

Was a food vehicle identified? – Check “Yes” if a specific food vehicle was identified or suspected for the outbreak.

If **Yes**, specify details of food vehicle in *Implicated Foods – Details* sections (Sections 17.1 and 17.2).

If **No**, skip to Section 18.

SECTIONS 17.1 AND 17.2: IMPLICATED FOODS – DETAILS

Only complete this section if a food item was identified as the primary mode of transmission. If more than one food was implicated, enter information for the second implicated food in Section 17.2. If more than two foods were implicated, please provide the details listed below for the other foods on additional sheets of paper.

For each implicated or suspected food, provide the following information:

- **Name of Food** – Excluding any method of preparation, indicate a single implicated or suspected food.
- **Ingredient(s)** – List all known ingredients for the implicated or suspected food. Please note that this is not a required field.
- **Contaminated Ingredient(s)** – Among the ingredients previously listed in the *Ingredient(s)* field, indicate the contaminated ingredient(s). If contaminated ingredients are unknown, check the box for “Unknown”.
- **Total # Primary Cases Exposed to Implicated Food** – Indicate total number of primary cases exposed to implicated food.

Example 1 – Implicated food was cantaloupe. Enter the information as follows:

- **Name of Food:** cantaloupe
- **Ingredient(s):** cantaloupe
- **Contaminated Ingredient(s):** cantaloupe

Example 2 – Implicated food was coleslaw and contaminated source ingredient was cabbage. Known ingredients in the coleslaw were cabbage, carrots, mayonnaise, salt, and pepper. Enter the information as follows:

- **Name of Food:** coleslaw
- **Ingredient(s):** cabbage, carrots, mayonnaise, salt, pepper
- **Contaminated Ingredient(s):** cabbage

Example 3 – Implicated food was coleslaw; however, the specific contaminated ingredient was not identified. Known ingredients in the coleslaw were cabbage, carrots, mayonnaise, salt, and pepper. Enter the information as follows:

- **Name of Food:** coleslaw
- **Ingredient(s):** cabbage, carrots, mayonnaise, salt, pepper
- **Contaminated Ingredient(s):** unknown

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

- **Method of Processing (prior to point-of-service)** – For the lowest level of food responsible for the outbreak (either contaminated ingredient or single ingredient implicated food), indicate the method(s) of processing. The method of processing intends to capture any modifications to the contaminated source food before it arrives at the final point of use location. Select all methods of processing that apply.
 - **1 – Pasteurized:** A food preservation process whereby fluid milk and others foods are heat-treated for a specified time and temperature to destroy all disease causing microorganisms and to reduce the total number of bacteria. These products should be labeled as having been pasteurized. For example, fluid milk and milk products, juice, pasteurized egg-product, in-shell pasteurized eggs, etc.
 - **2 – Unpasteurized:** Product that commonly is pasteurized for safety that has not gone through the pasteurization process. The product is not labeled as having been pasteurized. For example, fluid milk, cheese, juice, etc.
 - **3 – Shredded or diced:** Produce that has been manually or mechanically shredded or diced at a processor and is received at the point of use without the need for further preparation except possible washing prior to service. This can also include shredded or diced cheese or meat that arrives at the point of service already shredded or diced.
 - **4 – Pre-packaged:** Packaged at the processor level and received at the point of use in a sealed bag or container (e.g., bagged lettuce or other produce).
 - **5 – Irradiation:** A controlled exposure of food to gamma rays from a radioactive source or to ionizing radiation to accomplish the equivalent of pasteurization. It may be labeled with a “radura” symbol or otherwise labeled to indicate that it was irradiated.
 - **6 – Pre-washed:** The pre-washed food product when received at the point of use is considered a washed product (majority will be labeled as ‘pre-washed’) and may or may not specify on its label whether subsequent washing prior to use is necessary.
 - **7 – Frozen:** Process of freezing food to temperatures zero degrees Fahrenheit or below for the preservation of food and/or to provide protection against foodborne pathogens such as parasites. The product arrives at the final point of use location already frozen. For example, if the product arrived at the restaurant fresh then the restaurant later froze the product, the ‘method of processing’ would not be ‘frozen.’
 - **8 – Canned:** The product arrived at the point of use in a can. Please indicate ‘home-canned’ or ‘commercially-canned’ in the *Remarks and Conclusions* section (Section 24).
 - **9 – Acid treatment:** The product arrived at the point of use having been made with an acid ingredient that would lower the pH for preservation and/or pathogen control. For example, commercial potato salad with vinegar.
 - **10 – Pressure treated:** The product arrived at the point of use labeled it had been pressure treated. This process destroys bacterial pathogens of concern. For example, oysters, juice, etc.
 - **11 – Other or unknown:** Method of processing was not identified above or method of processing is unknown. Please provide additional information in the *Remarks and Conclusions* section (Section 24).

- **Method of Preparation¹ (at point-of-service; retail: restaurant, grocery store)** – For the implicated food, indicate the method of preparation. The method of preparation intends to capture any modifications to the implicated food after it arrives at the final point of use location, which will often be a retail establishment such as a restaurant or grocery store. In other words, how was the implicated food handled before it was served? Select only one method of preparation from the list below; multiple selections are NOT permitted in NORS. Please note that the provided examples are to be used as guides; allow the possibility that different establishments may practice different methods of preparation for the same food.
 - **1 – Prepared in the home:** Food that is prepared in a private home and not in a regulated retail food establishment, such as a restaurant or grocery store that is regulated by a food regulatory authority. For example, game that was slaughtered, skinned, and/or butchered in a private home.

- **2 – Ready to eat food: no manual preparation, no cook step:** Food preparation with no cook step wherein ready-to-eat food is received, stored, held and served. For example, manufacturer pre-sliced cheese, pre-packaged deli meats; whole raw fruits; pre-shucked raw oysters.
- **3 – Ready to eat food: manual preparation, no cook step:** Food preparation with no cook step wherein ready-to-eat food is received, stored, prepared, held, and served. For example, cut fresh fruits and vegetables, chicken salad made on-site from canned chicken.
- **4 – Cook and serve foods: immediate service:** Food preparation for same day service that involves a kill-step (cooked) wherein food is received, stored, prepared, cooked, and served. For example, food that is not cooled to order and served immediately after preparation, such as soft-cooked eggs and hamburgers.
- **5 – Cook and hot hold prior to service:** Food preparation for same day service wherein food is received, stored, prepared, cooked, held, and served. For example, hot dogs, fried chicken, soups, hot vegetables, and mashed potatoes.
- **6 – Advance preparation: cook, cool, serve:** Complex food preparation wherein food is received, stored, prepared, cooked, and cooled during an extended period of time (several hours or a day or more) prior to service. For example, sliced roast beef from a whole cooked roast.
- **7– Advance preparation: cook, cool, reheat, serve:** Complex food preparation wherein food is received, stored, prepared, cooked, and cooled several hours or a day or more in advance of service, then reheated immediately prior to service. For example, lasagna, casseroles, soups, gravies, sauces, and chili.
- **8 – Advance preparation: cook, cool, reheat, hot hold, serve:** Complex food preparation wherein food is received, stored, prepared, cooked, and cooled several hours or a day or more in advance of service, then reheated and held hot prior to service. For example, chili and refried beans.
- **9 – Advance preparation: cook-chill and reduced oxygen packaging (ROP):** Complex food preparation wherein food is processed on-site in a retail food establishment so that it goes through a packaging procedure that results in a reduced level of oxygen in a sealed package. For example, sauces, gravies; cheeses packaged under ROP. ROP is an inclusive term and can include other packaging processes such as cook-chill and sous-vide. Cook-chill is a process that uses a plastic bag filled with hot cooked food from which air is expelled and which is closed with a plastic or metal crimp. Sous-vide is a specialized process of ROP for partially cooked ingredients alone or combined with raw foods that require refrigeration or frozen storage until the package is thoroughly heated immediately before service.
- **10 – Other or unknown:** Method of preparation is not identified above or method of preparation is unknown. Please provide additional information in the *Remarks and Conclusions* section (Section 24).

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

- **Level of Preparation** – For the implicated food, indicate level of preparation. Select all levels of preparation that apply.
 - 1 – Foods eaten raw with minimal or no processing (e.g., washing, cooling).
 - 2 – Foods eaten raw with some processing (e.g., no cooking, fresh cut and/or packaged raw).
 - 3 – Foods eaten heat processed (e.g., cooked: a microbiological kill step was involved in processing).
- **Contaminated food imported to U.S.?** – Indicate if the implicated food was imported into the U.S. If the contaminated food was imported, specify the name of the country if known.

SECTION 18: LOCATION WHERE FOOD WAS PREPARED

Location Where Food was Prepared: Indicate all locations where the implicated food(s) were prepared. If there was a specific food item confirmed as the contaminated source, indicate only the location where that food item was prepared. Multiple selections are allowed. Briefly describe important aspects in the *Remarks* field below the list of locations. The examples provided should be used as guides; it is nearly impossible to provide examples that would be applicable for every outbreak scenario. With that in mind, please use your best judgment when indicating the 'location where food was prepared'.

- **Restaurant: 'Fast-food' (drive up service or pay at counter)** – Indicate if food was prepared at a fast food restaurant. Consider fast-food restaurants as any restaurant where patrons are not served by a server at a table and patrons are responsible for their own food tray, such as at McDonald's, Subway, etc.
- **Restaurant: Sit-down dining** – Indicate if food was prepared at a sit down dining restaurant. Consider a sit-down dining restaurant as any restaurant where restaurant staff directs patrons to their seat and the restaurant staff is responsible for clearing the tables, such as Red Lobster, Chili's, buffet restaurants, etc. Many traditional sit-down restaurants now offer patrons an opportunity to have their food prepared to-go, identify such 'location where food was prepared' as a sit-down dining restaurant.
- **Restaurant: Other or unknown type** – Indicate if food prepared at a restaurant, but the type of restaurant was not a 'fast-food' or sit-down dining restaurant or if unknown. It would be difficult to classify all restaurants; the examples above should be used as a guide. If you encounter a restaurant that does not fit into either 'fast-food' or 'sit-down' categorizations (a possible hybrid of the two), select this option and provide additional details in the *Remarks* field below the list of locations. For example, mall food court or stand-alone deli (based on establishment).
- **Private home** – Indicate if food prepared at a private home.
- **Banquet facility (food prepared and served on-site)** – Indicate if food was prepared and served on site. A banquet facility is typically a building/section of a building, equipped with an on-site kitchen/cooking facility, capable of serving individuals at an on-site dining area. For example, if a group of patrons dine in a sit-down restaurant's banquet room, indicate 'location where food was prepared' as 'Restaurant: Sit-down dining' and 'location where food was eaten' as 'Banquet facility.'
- **Caterer (food prepared off-site from where served)** – Indicate if food prepared off-site at a different location from where it was eaten. Event caterers typically prepare food off-site and deliver/set-up prepared food at another location.
- **Fair, festival, other temporary or mobile services** – Indicate if food prepared at a fair, festival, or other temporary or mobile food service.
- **Grocery store** – Indicate if food prepared at grocery store. For example deli department or seafood department of a grocery store.
- **Workplace, not cafeteria** – Indicate if food prepared at a workplace, but not at a work cafeteria. For example, a worker uses the workplace kitchenette (stove, toaster, etc.) to prepare lunch.
- **Workplace cafeteria** – Indicate if food prepared at a workplace cafeteria. Typically, the workplace cafeteria will be a separate cooking facility where cafeteria staff will prepare and serve food; the cafeteria should contain a dining area.
- **Nursing home (e.g., skilled nursing facility, long-term care facility)** – Indicate if food prepared at a nursing home such as a skilled nursing or long-term care facility.
- **Assisted living facility, home care** – Indicate if food prepared at an assisted living facility or home care.
- **Hospital** – Indicate if food prepared at a hospital.
- **Child day care center** – Indicate if food prepared at a child day care center.
- **School** – Indicate if food prepared at a school (kindergarten through college).
- **Prison, jail** – Indicate if food prepared at a jail or prison.
- **Church, temple, religious location** – Indicate if food prepared at a church, temple, or other religious location.
- **Camp** – Indicate if food prepared at a camp. A camp may include any designated place used for overnight stay outdoors, including but not limited to summer camps for youth with formal kitchen, a day camp that

serves food, a commercial firm that hosts trips such as rafting or horseback riding, family vacations where a fire pit or small burners are used to prepare food, etc.

- **Picnic** – Indicate if food prepared at a picnic. A picnic is typically a meal prepared outdoors with no overnight stay, such as food prepared during a company picnic/cookout or a couple prepares small sandwiches outdoors.
- **Other (describe in Remarks)** – If food was prepared at a location that cannot be described from the above choices, please indicate ‘Other’ and explain details in the *Remarks* field below the list of locations.
- **Unknown** – If information on location where food was prepared is not known, please indicate unknown.

Remarks – Indicate any other information related to the location where prepared, and if ‘Other’ location where food prepared was indicated, please describe here.

SECTION 19: LOCATION OF EXPOSURE (WHERE FOOD WAS EATEN)

Location of Exposure (where food was eaten): Indicate the location where the implicated food(s) were eaten. Multiple selections are allowed. Briefly describe important aspects in the *Remarks* field below the list of locations. The examples provided should be used as guides; it would be nearly impossible to provide examples that would be applicable for every outbreak scenario. With that in mind, please use your best judgment when indicating the ‘where food was eaten’.

See Section 18 (Location Where Food was Prepared) instructions for descriptions of types of locations.

Remarks – Indicate any other information related to the location where eaten, and if ‘Other’ location where food eaten was indicated, please describe here.

SECTION 20: CONTRIBUTING FACTORS

Contributing factors (CFs) are defined as the food safety practices and behaviors which most likely contributed to a foodborne illness outbreak. A CF should be identified only if the investigator has strong evidence (epidemiological, laboratory, and/or environmental assessment) 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.

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 visit to the location where suspected food vehicles are grown, harvested, processed, prepared and/or served;
- A review of the physical facilities and the equipment used;
- Interviews with those involved in the harvest, processing, handling and/or preparation of the implicated foods;
- 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;
- 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
- 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.

Are contributing factors known? – Indicate if a contributing factor was identified for the outbreak.

If **Yes**, specify contributing factors in *Contributing Factors – Details* section (Section 21); otherwise, skip to Section 22.

SECTION 21: CONTRIBUTING FACTORS – DETAILS

Select all CFs that are causally associated with the outbreak. 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. See *NORS Guidance for Contributing Factors* for definitions and examples of each factor at: <http://www.cdph.ca.gov/pubsforms/forms/Documents/NORSGuideContribFactors.pdf>.
- 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. Please explain why contamination factors could not be identified in the *Remarks and Conclusions* section (Section 24).

Proliferation/Amplification Factors (bacterial outbreaks only):

- 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. See *NORS Guidance for Contributing Factors* for definitions and examples of each factor at: <http://www.cdph.ca.gov/pubsforms/forms/Documents/NORSGuideContribFactors.pdf>.
- 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. Please explain why proliferation/amplification factors could not be identified in the *Remarks and Conclusions* section (Section 24).

Survival Factors (check all that apply):

- 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. See *NORS Guidance for Contributing Factors* for definitions and examples at:
<http://www.cdph.ca.gov/pubsforms/forms/Documents/NORSGuideContribFactors.pdf>.
- 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. Please explain why survival factors could not be identified in the *Remarks and Conclusions* section (Section 24).

SECTION 22: POINT OF CONTAMINATION (CONFIRMED OR SUSPECTED)

- **Confirmed or Suspected Point of Contamination** (check one) – Indicate if confirmed or suspected point of contamination occurred ‘Before preparation’ or at ‘Preparation.’ For example, if a multistate outbreak was linked by PFGE to samples obtained from a processing plant, one might conclude that the contamination occurred ‘before preparation.’ Often, it will be difficult to make this delineation without a traceback investigation, but indicate based on your investigation whether you would conclude that contamination occurred before preparation or at preparation.
 - **If before preparation**, specify if it occurred at ‘Pre-Harvest’, ‘Processing’, or ‘Unknown’. Further evidence might permit determining whether the point of contamination occurred at ‘pre-harvest’ (FDA traceback to farm fields) or ‘processing’ (FDA traceback to leaking roof at plant).
- **Reason(s) Suspected (check all that apply)** – Indicate the reason why the confirmed or suspected point of contamination was assumed.
 - **Environmental evidence** – for example, soil sample collected contaminated lettuce field
 - **Epidemiologic evidence** – for example, implicated food identified through a case-control study
 - **Laboratory evidence** – for example, laboratory confirmation obtained from food specimen or patient specimen
 - **Prior experience** makes this a likely source of contamination.

SECTION 23: SCHOOL

Complete this section only if “School” is checked in either the *Location Where Food was Prepared* section or the *Location of Exposure (Where Food Eaten)* section (Sections 18 and 19, respectively).

- **Did the outbreak involve a single or multiple schools?** – Indicate if a single school or multiple schools were involved in the outbreak. If multiple schools were involved in the outbreak, enter the number of schools.
- **Total Approximate Enrollment (for all involved students in all involved schools)** – Indicate the approximate number of students enrolled in the school or if the number of students is unknown.
- **Grade Levels for All Involved Students in All Involved Schools** – Indicate the grade level of the students in the outbreak; if more than one grade level applies, indicate all grade levels that apply.
 - **Preschool** – An educational institution for children too young to attend elementary school.
 - **Grade school** – Formal school for children from kindergarten to grade 12. Indicate all grades affected.

- **College/university/technical school** – Formal educational institution for students after high school age.
- **Unknown or undetermined** – Indicate unknown or undetermined if the grade level of the involved students are unknown or could not be determined.
- **Was implicated food item provided to the school through the National School Lunch/Breakfast Program?** – Indicate whether the implicated item was served as part of the National School Lunch/Breakfast Program, and used commodities purchased and distributed by USDA for use in schools.

If Yes, indicate if the implicated food item donated/purchased by: ‘USDA through the Commodity Distribution Program,’ ‘The state/school authority,’ ‘Other (specify source in space provided),’ or ‘Unknown or undetermined’. Select one only.

SECTION 24: REMARKS AND CONCLUSIONS

Please provide a brief summary of the investigation findings and the conclusions drawn, include important aspects not covered elsewhere in the report. Indicate if any persons in sensitive occupations or situations (e.g., foodhandlers, children attending daycare) were involved or if any adverse outcomes occurred in special populations (e.g., pregnant women, immunocompromised persons). Attach any documents that provide additional information.

SECTION 25: REPORTING AGENCY AND OTHER KEY INVESTIGATORS

Local Health Jurisdiction – Indicate local health jurisdiction reporting outbreak.

Provide the following investigator information:

- **Lead Investigator name**
- **Investigator title**
- **Telephone number**
- **Fax number**
- **E-mail**

Date – Indicate date that the outbreak report form was completed.

Other Key Investigators – List information for other key people involved in the investigation, such as name, title, organization, etc.

SECTION 26: PHEP – SEVEN MINIMAL ELEMENTS CHECKLIST

The *CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement – Performance Measures Specifications and Implementation Guidance* (pp. 56-60) requires that seven minimal elements be included in outbreak investigation reports. These seven elements are covered in various sections of this report form. The checklist is provided for your convenience to confirm that the seven elements have been included in the report.

The table on page 20 lists the seven minimal elements along with the primary sections in the report that cover each element. This table is provided as a general guide. Some report sections listed for an element may not be relevant for the particular investigation being reported.

Element	Section(s) Covering Element
<p>1. Context / background – Information that helps to characterize the incident, including:</p> <ul style="list-style-type: none"> • Population affected (e.g., estimated number of persons exposed and number of persons ill) 5, 9 • Location (e.g., setting or venue) 18-19 • Geographical area(s) involved 4 • Suspected or known etiology 13-14 	
<p>2. Initiation of investigation – Information regarding receipt of notification and initiation of the investigation, including:</p> <ul style="list-style-type: none"> • Date and time initial notification was received by the agency 3 • Date and time investigation was initiated by the agency 3 	
<p>3. Investigation methods – Epidemiological or other investigative methods employed, including:</p> <ul style="list-style-type: none"> • Any initial investigative activity (e.g., verified laboratory results) 2, 5, 8, 15 • Data collection and analysis methods (e.g., case-finding, cohort/case-control studies, environmental investigation or testing, etc.) 2, 10 • Tools that were relevant to the investigation (e.g., epidemic curves, attack rate tables, questionnaires) 2 • Case definitions (as applicable) 5 • Exposure assessments and classification (as applicable) 2, 18-19, 20-21 • Reviewing reports developed by first responders, lab testing of environmental media, reviews of environmental testing records, industrial hygiene assessments, questionnaires 2 	
<p>4. Investigation findings/results – All pertinent investigation results, including:</p> <ul style="list-style-type: none"> • Epidemiological results 5-9, 13, 16-17, 19 • Laboratory results (as applicable) 13-15 • Clinical findings (as applicable) 5-8 • Other analytic findings (as applicable) 10-11 	
<p>5. Discussion and/or conclusions Analysis and interpretation of the investigation results, and/or any conclusions drawn as a result of performing the investigation. In certain instances, a conclusions section without a discussion section may be sufficient.</p>	2, 13, 16, 24
<p>6. Recommendations for controlling disease and/or preventing/mitigating exposure – Specific control measures or other interventions recommended for controlling the spread of disease or preventing future outbreaks and/or for preventing/mitigating the effects of an acute environmental exposure.</p>	12
<p>7. Key investigators and/or report authors – Names and titles are critical to ensure that lines of communication with partners, clinicians and other stakeholders can be established.</p>	25

SECTION 27: STATE USE ONLY

State staff will complete this section.

ATTACHMENTS

Please attach any pertinent documents, such as tables for case-control or cohort studies, agency reports on the outbreak, MMWR articles, and/or journal publications. The information in these documents can be particularly helpful to outbreak coordinators who were not involved in the outbreak. Additional documents may be attached as they become available.