Infectious Agent
Shiga toxin-producing *Escherichia coli* (STEC) bacteria. *E. coli* are Gram-negative, rod-shaped bacteria that naturally exist in the mammalian digestive system. Pathogenic strains can be identified by the presence of at least one of two Shiga toxin-producing genes, *stx1* and *stx2*. The most common serogroups isolated from persons with diarrheal illness in North America are O157, O26, O111, O103, O45, O145, and O121.

Transmission
Transmission is fecal-oral and can occur through the ingestion of fecally contaminated food or water. Transmission can also occur via direct contact with an infected person, fomite, animal or an animal’s environment. Person to person spread is common within households and daycare centers.

Incubation Period
Incubation can range from as short as 1 day to as long as 10 days; *E. coli* O157:H7 is usually 3 to 4 days, with 6% of infections developing hemolytic uremic syndrome (HUS) within 3 weeks of infection.

Communicability
The duration of excretion of the pathogen is typically 1 week or less in adults, but 3 weeks in one-third of children. Prolonged carriage is uncommon.

Clinical Illness
Symptoms can vary but predominant symptoms include severe abdominal pain and non-bloody diarrhea which can become bloody after 3 to 4 days.

Severity
Hemolytic uremic syndrome (HUS) is a serious complication of STEC infections and can begin as symptoms resolve, usually within 3 weeks of infection. About 15% of young children and a smaller proportion of adults with STEC O157 diarrhea develop HUS. HUS typically requires dialysis and death can occur in 3 to 5% of cases.
DEFINITIONS

Clinical Case Definition
An infection of variable severity characterized by diarrhea (often bloody) and abdominal cramps. Illness can be complicated by hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP); asymptomatic infections can also occur and the organism can cause extra-intestinal infections.

Laboratory Confirmation
- Isolation of Shiga toxin-producing Escherichia coli from a clinical specimen
  - *Escherichia coli* O157:H7 isolates are assumed to be Shiga toxin-producing. Therefore, isolation alone qualifies a case as “confirmed.”
  - *Escherichia coli* non-O157:H7 isolates must also have Shiga toxin-production verified in order to qualify the case status as “confirmed.” Shiga toxin can be demonstrated by EIA or PCR testing.
  - EIA and/or PCR positive results for Shiga toxin-production, in the absence of an isolate, can only qualify a case as “probable.”

Note: As required by TAC, all *E. coli* O157:H7, isolates or specimens from cases where Shiga-toxin activity is demonstrated must be submitted to the DSHS laboratory.

Case Classifications
- **Confirmed:** A case that meets the laboratory criteria for diagnosis; when available, O and H antigen serotype characterization should be reported.
- **Probable:**
  - A case with isolation of *E. coli* O157 from a clinical specimen, without confirmation of the H antigen or Shiga toxin-production, **OR**
  - A clinically compatible case that is epidemiologically linked to a confirmed or probable case, **OR**
  - Identification of an elevated antibody titer to a known Shiga toxin-producing *E. coli* serotype from a clinically compatible case, **OR**
  - Identification of Shiga toxin in a specimen from a clinically compatible case without the isolation of the Shiga toxin-producing *E. coli*, **OR**
  - A clinically compatible illness in a person with detection of Shiga toxin or Shiga toxin genes in a clinical specimen using a CIDT and no known isolation of *Shigella* from a clinical specimen, **OR**
  - A clinically compatible illness in a person with detection of *E. coli* O157 or STEC/EHEC in a clinical specimen using a CIDT.
- **Suspect:** A case with no known clinical compatibility and detection of
  - Shiga toxin or Shiga toxin genes in a clinical specimen using a CIDT and no known isolation of Shigella from a clinical specimen, **OR**
  - Detection of *E. coli* O157 or STEC/EHEC in a clinical specimen using a CIDT.

Notes:
- Cases meeting confirmed or probable criteria for both STEC and HUS should be reported under each condition.
- A case should not be counted as a new case if a positive laboratory result is reported within 180 days of a previously reported positive laboratory result in the same individual, unless additional information is available indicating a separate infection.
SURVEILLANCE AND CASE INVESTIGATION

Case Investigation
Local and regional health departments should promptly investigate all reports of Shiga toxin-producing E. coli infections. Investigations should include an interview of the case or a surrogate to get a detailed exposure history. Please use the Shiga Toxin-Producing Escherichia coli (E. coli) and/or Hemolytic Uremic Syndrome (HUS) Investigation Form available on the DSHS website: http://www.dshs.state.tx.us/idcu/investigation/.

Case Investigation Checklist
- Confirm laboratory results meet the case definition.
- Verify that the laboratory has forwarded an isolate or specimen from cases where Shiga toxin activity is demonstrated to the DSHS laboratory. If an isolate has not been sent, please request a specimen be submitted as required.
- Review medical records or speak to an infection preventionist or healthcare provider to verify case definition, identify possible risk factors and describe course of illness.
- Interview the case to get detailed food history and risk factor information.
  - Use the Shiga Toxin-Producing Escherichia coli (E. coli) and/or Hemolytic Uremic Syndrome (HUS) Investigation Form to record information from the interview.
  - If the case is not available or is a child, conduct the interview with a surrogate who would have the most reliable information on the case, such as a parent or guardian.
  - Provide education to the case or his/her surrogate about effective hand washing, food safety practices, and animal contact/handling precautions. See Prevention and Control Measures.
- Fax completed forms to DSHS EAIDB at 512-776-7616 or email securely to an EAIDB foodborne epidemiologist.
  - For lost to follow-up (LTF) cases, please complete as much information obtained from medical/laboratory records (e.g., demographics, symptomology, onset date, etc.) on investigation form and fax/email securely to DSHS EAIDB, noting case is LTF.
- Identify whether there is a public health concern: persons should not work as food handlers, child-care or health-care workers, or attend child-care as long as they have diarrhea. See Exclusions.
- If case is part of an outbreak or cluster, see Managing Special Situations section.
- All confirmed and probable case investigations must be entered and submitted for notification in the NEDSS Base System (NBS). Please refer to the NBS Data Entry Guidelines for disease specific entry rules.

Prevention and Control Measures
- Routine hand washing with soap and warm water, especially:
  - Before preparing, handling or eating any food.
  - After going to the bathroom.
  - After changing a diaper.
  - After caring for someone with diarrhea.
  - After handling raw food, especially poultry and beef.
  - After any contact with animals, their living areas or their food.
- Avoid consuming raw milk, unpasteurized dairy products, and unpasteurized juices (like fresh apple cider). Prolonged heat treatment is required to destroy Shiga toxin.
- Avoid consumption of raw sprouts, especially by those most susceptible to severe complications of foodborne diseases (young children, the elderly, pregnant women, and person with compromised immune system).
Follow food safety principles in the kitchen, especially:
- Cook meat thoroughly. Ground beef and meat that has been needle-tenderized should be cooked to a temperature of at least 160°F (70°C). Use a thermometer to verify the temperature, as color is not a very reliable indicator of how thoroughly meat has been cooked.
- Prevent cross-contamination in food preparation areas by thoroughly washing hands, counters, cutting boards, and utensils after they touch raw meat.
- Thoroughly wash fresh leafy greens, fruits and vegetables with water.
- Avoid swallowing water when swimming and when playing in lakes, ponds, streams, swimming pools, and backyard "kiddie" pools.
- Do not participate in recreational water activities such as swimming while diarrhea is present and for two weeks after diarrhea has resolved.

Exclusions

School/child-care: No exclusion specified for Shiga toxin-producing \textit{Escherichia coli} but the standard exclusion for diarrhea or fever applies:
- Children with diarrhea should be excluded from school/child-care until they are free from diarrhea for 24 hours without the use of diarrhea suppressing medications.
- Children with a fever from any infection should be excluded from school/child-care for at least 24 hours after fever has subsided without the use of fever suppressing medications

Food Employees: Symptomatic food employees infected with Shiga toxin-producing \textit{E. coli} are to be excluded from work. Asymptomatic food employees diagnosed with an infection from Shiga toxin-producing \textit{E. coli} are to be excluded from working in a food establishment serving a highly susceptible population or restricted if they do not serve a highly susceptible population.

Food employees can be reinstated with approval from the Regulatory Authority and if one of the following conditions is met:
- Medical documentation stating that the food employee is free of infection from Shiga toxin-producing \textit{E. coli} based on test results showing two consecutive, negative stool specimen cultures. The stool specimens should be collected at least 24 hours apart and not sooner than 48 hours after the last dose of antibiotics, if antibiotics were given. (Antibiotics are not recommended for treating illness due to STEC or asymptomatic carriage of STEC.) OR
- More than 7 days have passed since the food employee became asymptomatic (without the use of diarrhea suppressing medications) OR
- The food employee did not develop symptoms and more than 7 days have passed since being diagnosed.

Please see Guide to Excluding and Restricting Food Employees in Appendix A.
MANAGING SPECIAL SITUATIONS

Outbreaks
If an outbreak is suspected, notify the appropriate regional DSHS office or DSHS EAIDB at (800) 252-8239 or (512) 776-7676.

The local/regional health department should:
- Interview all cases suspected as being part of the outbreak or cluster.
- Request medical records for any case in your jurisdiction that died, was too ill to be interviewed, or for whom there are no appropriate surrogates to interview.
- Prepare a line list of cases in your jurisdiction. Minimal information needed for the line list might include patient name or other identifier, DSHS or laboratory specimen identification number, specimen source, date of specimen collection, date of birth, county of residence, date of onset (if known), symptoms, underlying conditions, treatments and outcome of case, and risky foods eaten, foods eaten leading up to illness, or other risky exposures, such as animal contact and travel, reported by the case or surrogate.

Line list example:

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Age</th>
<th>Sex</th>
<th>Ethnicity</th>
<th>Onset</th>
<th>Symptoms</th>
<th>Food</th>
<th>Animal</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NT</td>
<td>34</td>
<td>F</td>
<td>W/N</td>
<td>2/4/16</td>
<td>Bl. D, F</td>
<td>Chicken, eggs</td>
<td>Dog</td>
<td>Dog food</td>
</tr>
<tr>
<td>2</td>
<td>PR</td>
<td>2</td>
<td>M</td>
<td>U/U</td>
<td>1/30/16</td>
<td>V,D,F</td>
<td>Chicken, spinach</td>
<td>None</td>
<td>Brother ill</td>
</tr>
</tbody>
</table>

- If the outbreak was reported in association with an apparent common local event (e.g., party, conference, rodeo), a restaurant/caterer/home, or other possible local exposure (e.g., pet store, camp), contact hospitals in your jurisdiction to alert them to the possibility of additional STEC cases.
- If isolates have not already been submitted to the DSHS laboratory for confirmation and PFGE, request hospital/clinical labs submit isolates for confirmation and PFGE testing. See Laboratory Procedures.
- Work with any implicated facilities to ensure staff, students, residents, and volunteers receive hand hygiene education, and review hygiene and sanitary practices currently in place including:
  - Policies on, and adherence to, hand hygiene
  - Storage and preparation of food
  - Procedures for changing diapers and toilet training
  - Procedures for environmental cleaning
- Recommend that anyone displaying symptoms seeks medical attention from a healthcare provider.
- Restrict individuals from handling food, engaging in child-care, healthcare work, or attending child-care, as long as they are symptomatic. See Exclusions in Case Investigation section.
- Enter outbreak into NORS at the conclusion of the outbreak investigation. See Reporting and Data Entry Requirements section.

PFGE clusters:
- For clusters of cases with indistinguishable PFGE patterns detected by CDC/PulseNet and/or the DSHS laboratory, a member of the DSHS EAIDB foodborne team will notify appropriate DSHS regional epidemiologists, usually by email, who will then notify appropriate local health departments of cases within their jurisdiction.
• Local/regional health departments with cases in their jurisdiction should:
  o Interview the case patient, even if they have already been interviewed as part of a routine disease investigation, using the cluster specific questionnaire attached in the email notification.
    ▪ Fax the completed questionnaire promptly within timeframe designated in the cluster notification to DSHS EAIDB at 512-776-7616 or email securely to an EAIDB foodborne epidemiologist.
  o If the health department having jurisdiction of a case is unable to reach a case-patient after 3 attempts during normal working hours, and they are not able to call after hours, please call the DSHS regional office or DSHS EAIDB to discuss further.
  o If an interview is unattainable or the case is lost to follow-up, fax the completed cover sheet and any case information to DSHS EAIDB.
  o Local/regional health department with cases will be notified by the EAIDB foodborne team of any CDC or DSHS conference calls and may participate, if able.

Notes:
• If a food item or food establishment is implicated, the lead epidemiologist for foodborne diseases will notify the DSHS Division of Regulatory Services about the outbreak and the possibility of a common contaminated food source for the cases.
• Decisions about testing implicated food items can be made after consultation with an EAIDB foodborne epidemiologist and the DSHS Laboratory. The general policy is to test only food samples implicated in suspected outbreaks, not in single cases.
REPORTING AND DATA ENTRY REQUIREMENTS

Provider, School, Child-Care Facility, and General Public Reporting Requirements
Confirmed, probable, and clinically suspected cases are required to be reported within 1 week to the local or regional health department or DSHS EAIDB at (800) 252-8239 or (512) 776-7676.

Local and Regional Reporting and Follow-up Responsibilities
Local and regional health departments should:

- Enter the case into NBS and submit a NBS notification on all confirmed, probable, and suspect cases.
  - Please refer to the NBS Data Entry Guidelines for disease-specific entry rules.
  - A case should not be counted as a new case if a positive laboratory result is reported within 180 days of a previously reported positive laboratory result in the same individual, unless additional information is available indicating a separate infection.
  - A notification can be sent as soon as the case criteria have been met. Additional information from the investigation may be entered upon completing the investigation.
- Fax completed forms to DSHS EAIDB at 512-776-7616 or email securely to an EAIDB foodborne epidemiologist.

When an outbreak is being investigated, local and regional health departments should:

- Report outbreaks within 24 hours of identification to the regional DSHS office or to EAIDB at 512-776-7676.
- Enter outbreak information into the National Outbreak Reporting System (NORS) at the conclusion of the outbreak investigation.
  - For NORS reporting, the definition of an outbreak is two or more cases of similar illness associated with a common exposure.
  - The following should be reported to NORS:
    - Foodborne disease, waterborne disease, and enteric illness outbreaks with person-to-person, animal contact, environmental contact, or an indeterminate route of transmission.
    - Outbreaks as indicated above with patients in the same household.
  - Enter outbreaks into NORS online reporting system at https://wwwn.cdc.gov/nors/login.aspx
  - Forms, training materials, and other resources are available at http://www.cdc.gov/nors/
- To request a NORS account, please email FoodborneTexas@dshs.state.tx.us
  - Please put in Subject Line: NORS User Account Request
  - Information needed from requestor: name, email address, and agency name
  - After an account has been created, a reply email will be sent with a username, password, and instructions for logging in.
LABORATORY PROCEDURES

All *E. coli* 0157:H7 isolates or specimens from cases where Shiga toxin activity is demonstrated must be submitted to the DSHS laboratory.

In an outbreak or other special situation, the DSHS Laboratory can culture raw stool or stool in transport medium (e.g., Cary-Blair media) for Shiga toxin-producing *E. coli*. Contact an EAIDB foodborne epidemiologist prior to submitting raw stool or stool in transport medium for culture.

Specimen Collection
- Submit pure cultures on an agar slant at ambient temperatures.
- If a pure culture is not available but Shiga toxin activity is demonstrated,
  - Submit stool specimen in Cary-Blair, Aimes, or Stuart transport, on wet ice packs, OR
  - Submit stool specimens on broth or MacConkey broth, < 7 days old on wet ice packs, > 7 days old on dry ice.
- For raw stool or stool in transport medium, please refer to table below:

<table>
<thead>
<tr>
<th>Specimen type</th>
<th>Transport time to lab from time of collection</th>
<th>Transport temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw stool</td>
<td>≤24 hours</td>
<td>4°C (ice pack)</td>
</tr>
<tr>
<td>Raw stool</td>
<td>&gt;24 hours</td>
<td>Freeze immediately at ≤-70°C. Ship on dry ice.</td>
</tr>
<tr>
<td>Stool in transport solution/medium</td>
<td>Time of collection to ≤3 days</td>
<td>Room temp or 4°C (ice pack)</td>
</tr>
<tr>
<td>Stool in transport solution/medium</td>
<td>&gt;3 days</td>
<td>Freeze immediately at ≤-70°C. Ship on dry ice.</td>
</tr>
<tr>
<td>All</td>
<td><em>The above transport times are optimal for recovery of pathogenic organisms. In the interest of public health, specimens will be accepted up to 30 days from date of collection.</em></td>
<td><em>The above transport temperatures are optimal for the recovery of pathogenic organisms. In the interest of public health, specimens will be accepted at non-optimal temperature transport.</em></td>
</tr>
</tbody>
</table>

* Note: Pathogen recovery rates decrease over time. For best results, submit ASAP.

Submission Form
- Use DSHS Laboratory G-2B form for specimen submission.
- Make sure the patient’s name, date of birth and/or other identifier match exactly what is written on the transport tubes and on the G-2B form.
- Fill in the date of collection and select the appropriate test.
- If submitting as part of an outbreak investigation, check “Outbreak association” and write in name of outbreak.
- Payor source:
  - Check “IDEAS” to avoid bill for submitter.
Specimen Shipping

- Ship specimens via overnight delivery.
- DO NOT mail on Friday unless special arrangements have been pre-arranged with DSHS Laboratory.
- Ship specimens to:
  Laboratory Services Section, MC-1947
  Texas Department of State Health Services
  Attn. Walter Douglass (512) 776-7569
  1100 West 49th Street
  Austin, TX 78756-3199

Causes for Rejection:

- Incorrect source of specimen
- Specimen not in correct transport medium
- Missing or discrepant information on form/specimen
- Transport media was expired
- Specimen too old

FOOD SAMPLES AND ENVIRONMENTAL SWABS:

Testing of food and environmental swabs is available at the DSHS laboratory.

For *E. coli* O157:H7, the DSHS laboratory can test:
- Environmental Swabs
- Foods

For the “Big 6” STECs (O26, O45, O103, O111, O121, and O145), the DSHS laboratory can test:
- Environmental Swabs
- Meat Samples
- Milk Samples
- Other Foods- decisions to test other food samples not listed above would be evaluated a case by case basis

Decisions about testing implicated food items can be made after consultation with an EAIDB foodborne epidemiologist and the DSHS Laboratory.

General policy

- Test only food samples or environmental swabs from facilities implicated in a suspected outbreak (not associated with single cases).
- In outbreaks, the DSHS lab will not test food samples or environmental swabs unless a pathogen has been identified in a clinical specimen.
- Food samples or environmental swabs must be collected by a registered sanitarian.

For further questions, please contact an EAIDB foodborne epidemiologist to discuss further.
UPDATES

January 2018

- Updated case definition to match Epi Case Criteria Guide for 2018
  - Added two bullet points to Probable case classification to address CIDTs in cases with known clinical compatibility.
  - Added two bullet points to Suspect case classification to address CIDTs in cases with no known clinical compatibility.
- Updated the criteria to distinguish a new case from an existing case; only counting a case once per 180 days, in the Case Definitions and Reporting and Data Entry Requirements section.
- Updated the testing of food and environmental swabs at the DSHS laboratory section.