

Case Study – Summary Chronology
***Escherichia coli* O157:H7 Outbreak in Spinach**
United States
September 2006

Product: Fresh, Bagged Spinach

Cases: 205 illnesses, 104 hospitalizations, 31 cases of kidney failure and 3 deaths

Product Distribution: United States (U.S.), Canada, Mexico, and Taiwan, China

Trace back: 3 processors in the State of California, U.S.

1. Initial clues an outbreak was underway (August 19, 2006 – September 7, 2006)

- Two consumers in different states became ill and saw a healthcare provider
- Healthcare providers sent stool specimens to a clinical laboratory and *E. coli* O157 was isolated
- *E. coli* O157 strain was sent to a public health laboratory
- Public health laboratory performed DNA fingerprinting and submitted the pattern to PulseNet (U.S. network of public health laboratories that sub-type bacteria using pulse-field gel electrophoresis)
- 28 additional people in 11 other states became ill and sought medical attention
- The State of Wisconsin's clinical laboratories isolated *E. coli* O157:H7 from stool samples of seven patients and sent samples to Wisconsin's public health laboratory

2. First cases confirmed (September 8 – 12, 2006)

- The State of Oregon identifies a cluster of two *E. coli* O157:H7 cases with matching PFGE patterns
- Wisconsin identifies an increase in HUS cases and a small cluster of *E. coli* O157:H7 cases
- Wisconsin posted a message on the PulseNet Web Message Board, the DNA fingerprints were submitted electronically to the PulseNet national database at CDC
- Wisconsin epidemiologists notify CDC

- PulseNet confirms *E. coli* 0157:H7 strains from Wisconsin all have the same fingerprint
- Using PulseNet CDC looks for the strain in other states
- CDC confirms matching PFGE patterns in other states
- Two state investigators independently inform CDC they suspect bagged fresh spinach as the source of infection

3. **FDA Becomes Involved (September 13, 2006)**

- FDA's Office of Crisis Management/Office of Emergency Operations began coordinating the agency's internal and external investigational, scientific and communications activities. Internal coordination involved FDA's Emergency Operations Center, CFSAN, Office of Public Affairs, ORA Office of Regional Operations and multiple FDA field offices. External coordination involved HHS Secretary's Operations Center, CDC Director's Emergency Operations Center, State of California and other states.
- FDA is contacted by an epidemiologist in the Wisconsin Department of Health
- CDC notifies FDA about the Wisconsin and Oregon cases and possible link with bagged spinach
- Within hours after confirmation of the outbreak, FDA was seeing an increase in the number of cases

4. **Investigation (September 14, 2006 – October 12, 2006)**

- FDA alerts the public
- FDA immediately alerted our counterparts in Canada and Mexico and the INFOSAN Emergency Contact Point for the USA and once it was determined (4 days later) the product was shipped to three other countries INFOSAN sent Emergency Alerts to the INFOSAN Contact Points in affected countries
- Both Canada and Mexico restricted the importation of U.S. produced fresh spinach from all locations.
- CDC establishes and case definition for outbreak
- CDC works with States to create a standard questionnaire and develop a process for identifying and reporting cases

- FDA Outbreak Response Procedure activated and CDC contacted to discuss and coordinate the investigation, gather information related to illnesses, identify the possible source of the contamination, determine the need for product recalls, and determine the need for public communication.
- FDA works with the California Department of Health Services, Food and Drug Branch to initiate notification of the implicated firms
- FDA and the California Department of Health Services activate CALFERT (a joint California and FDA response team to investigate the source and extent of potentially contaminated product). A hydrologist from CDC was also part of the team.
- Spinach-processing firms notified about the outbreak and recommended they consider recalling spinach products
- FDA and CDC conducted on-site investigations of processing firms
- CDC alerts Public Health Officials in all States
- States with *E. coli* 0157:H7 cases were asked to rapidly perform DNA fingerprinting and report cases to CDC
- Daily conference calls with FDA, CDC, and State were held
- Implicated firms initiated recalls
- FDA, CDC, USDA, and States work together to conduct inspections, collect samples, and investigate the environment, water, and animal management issues
- FDA issued updated consumer alerts as information about the outbreak and source was received.
- The Canadian Food Inspection Agency (CFIA) initiated discussions with FDA on the outbreak including detailed scientific information on its cause. CFIA carried out joint inspections with FDA in the Salinas Valley to allow Canada to obtain an in-depth understanding of the situation at both the processing establishments and in the field.
- As the investigations proceeded and it became clear the problem was isolated to only a portion of California, Canada entered into discussions with the U.S., both with FDA and also working with the U.S. Department of Agriculture Foreign Agricultural Service to see if some type of certification system could be developed that would permit spinach from non-affected areas to be exported to Canada.

- CFIA, working with FDA, developed a grower self-certification program that allowed growers outside of the affected growing areas (principally the Salinas Valley) to self-certify their product, placing an attestation on the CFIA's "Confirmation of Sale" document, that stated "Grown in xxxxxx", where the name of the state (or location of the state within California) in which the product was grown was indicated. Canada monitored imports through visual examination of imported lots, and through sampling and testing, to ensure that self-certified product was coming from areas other than the affected area and that the product was safe for human consumption.

5. Investigation Findings and Conclusions

- Epidemiological finds and laboratory evidence indicates all spinach implicated was from one firm in California
- Test results from the field investigations were positive for *E. coli* 0157:H7
- Animal waste and water were important contributing factors. Observations suggest the contamination occurred in the field on the surface of the produce or through contamination of ground water or irrigation water, or a combination of those.

Outbreak response and investigation requires a significant level of coordination and cooperation at all levels.