

Cyclospora: An FDA Overview

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June 17, 2021

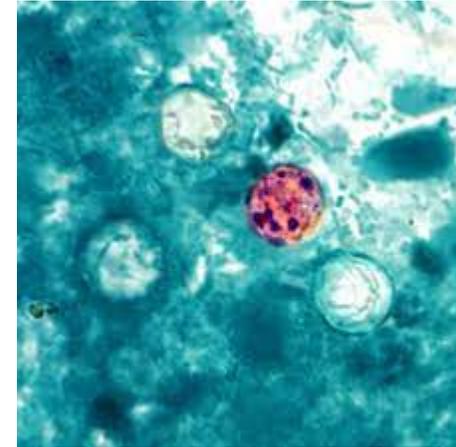
Overview



1. Brief Background
2. History in the US
3. Review of 2020 Bagged Salad Mix Outbreak
4. *Cyclospora* Next Steps and Prevention

Background

- Cyclosporiasis is an intestinal illness caused by the parasite *Cyclospora cayetanensis* (*C. cayetanensis*), which only occurs in humans, and the most common symptom is diarrhea.
- When the parasite is found in water or food, it means that the water or food has been contaminated with human feces.



What Makes *Cyclospora* Different?

- Unlike bacterial pathogens, WGS cannot be performed on *Cyclospora*.
- Outbreaks must be identified via epidemiology.
 - Travel history
 - Food questionnaires
- Subtyping methodologies are underdevelopment.

Cyclospora in the United States

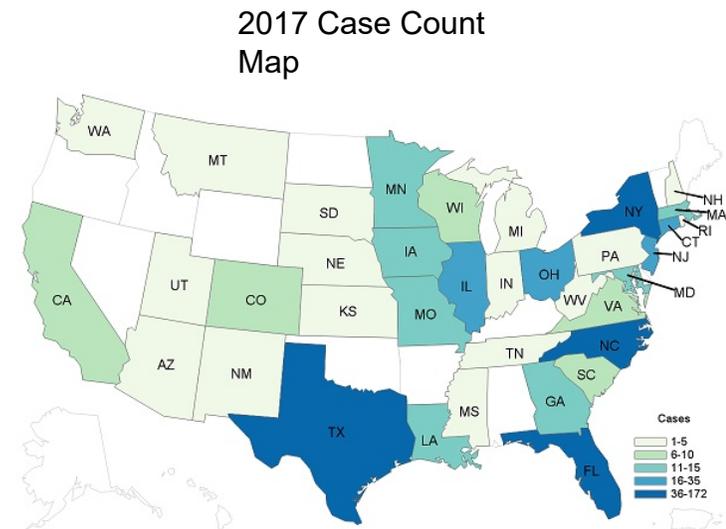
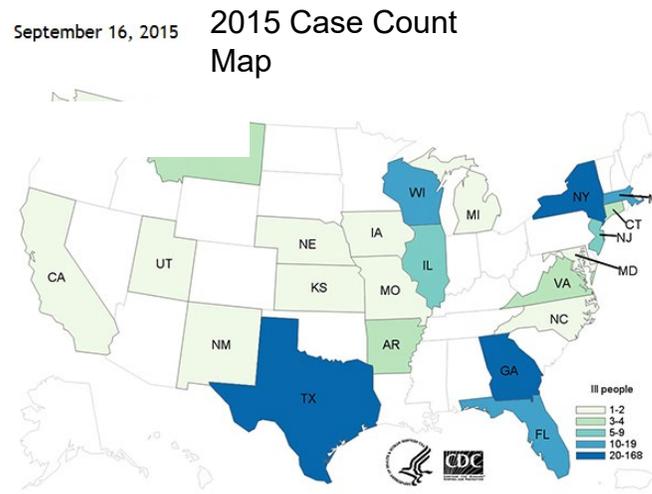
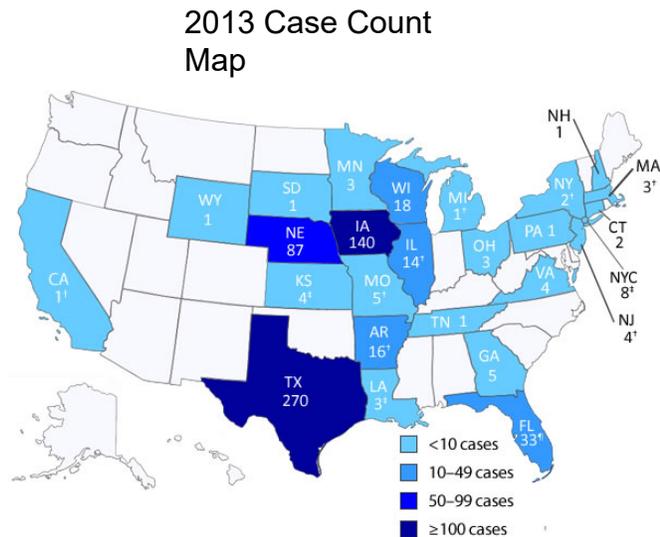
- FDA has responded to produce-associated outbreaks during summer months consistently since 2012.
- Previous outbreaks have included:
 - Herbs: fresh cilantro and basil
 - Prepackaged salads and leafy greens
 - Raspberries
 - Vegetable trays (fresh vegetables)



Cyclosporiasis Outbreaks 2013-2020



- 2013: 631 Cases in 25 states
- 2014: 207 Cases in 29 states
- 2015: 319 Cases in 23 states
- 2016: 134 cases in 34 states
- 2017: 597 cases in 36 states
- 2018: 2299 cases in 33 states
- 2019: 2408 cases in 37 states
- 2020: 1241 cases in 34 states



Source: CDC.gov

<https://www.cdc.gov/parasites/cyclosporiasis/outbreaks/index.html>

New Methodologies

- BAM Chapter 19b: Molecular Detection of *Cyclospora cayetanensis* in Fresh Produce Using Real-Time PCR
– June 2017
- BAM Chapter 19c: Dead-end Ultrafiltration (DEUF) for the Detection of *Cyclospora cayetanensis* from Agricultural Water
– July 2019



Cyclospora 2020:
FDA Outbreak Investigation Related to
Fresh Express Pre-Packaged Salad Mix



Cyclospora Season 2020

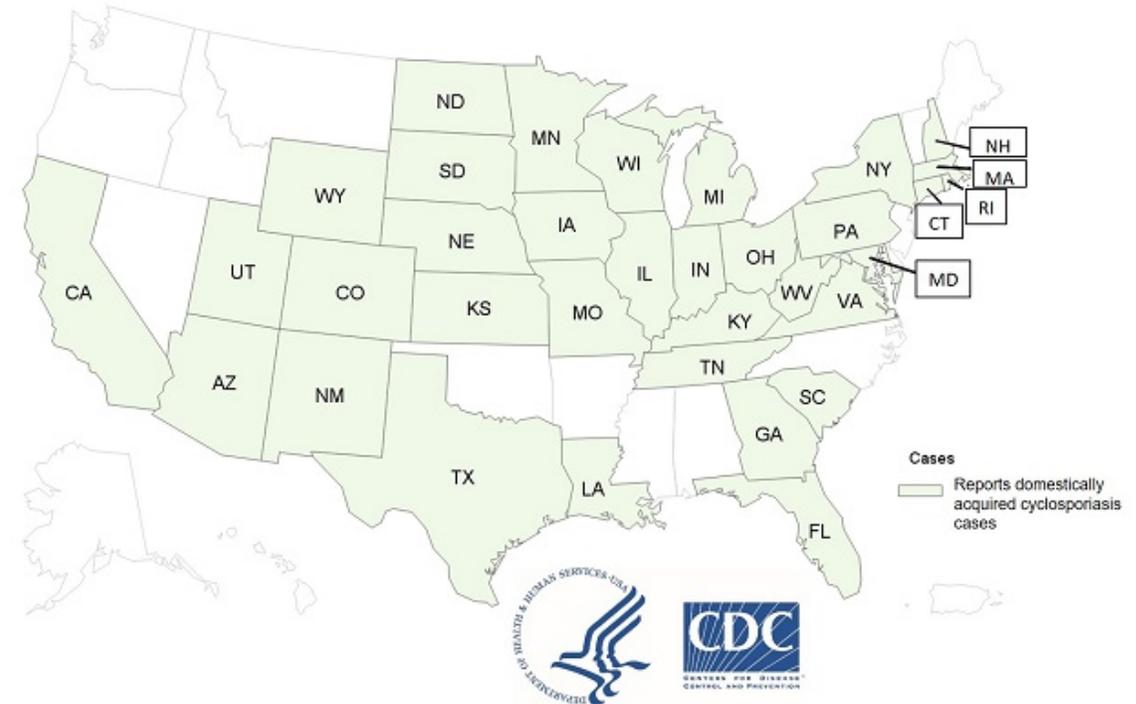


Epidemiology:

- Total Cases of Illness: 1,241*
- States reporting cases: 34
- Deaths: 0
- Hospitalizations: 90
- Median illness onset date is June 13, 2020 (range: May 1–August 31, 2020).

*Laboratory-confirmed cases of cyclosporiasis in people who had no history of international travel during the 14-day period before illness onset have been reported to CDC by 35 jurisdictions, including 34 states and New York City, since May 1, 2020

Geographic Distribution of Reported Cases of Domestically Acquired Cyclosporiasis—Onset May – August, 2020**

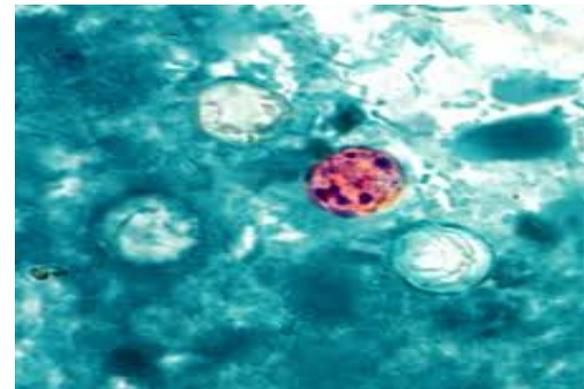


Source: CDC.gov

**Data are current as of 9/23/2020 (1:00 PM EDT). States/jurisdictions highlighted on the map have each reported at least one case. New York State includes case reports from New York City. Data are preliminary and subject to change. For questions related to the number of cases reported in each state, please contact that state's health department.

Background

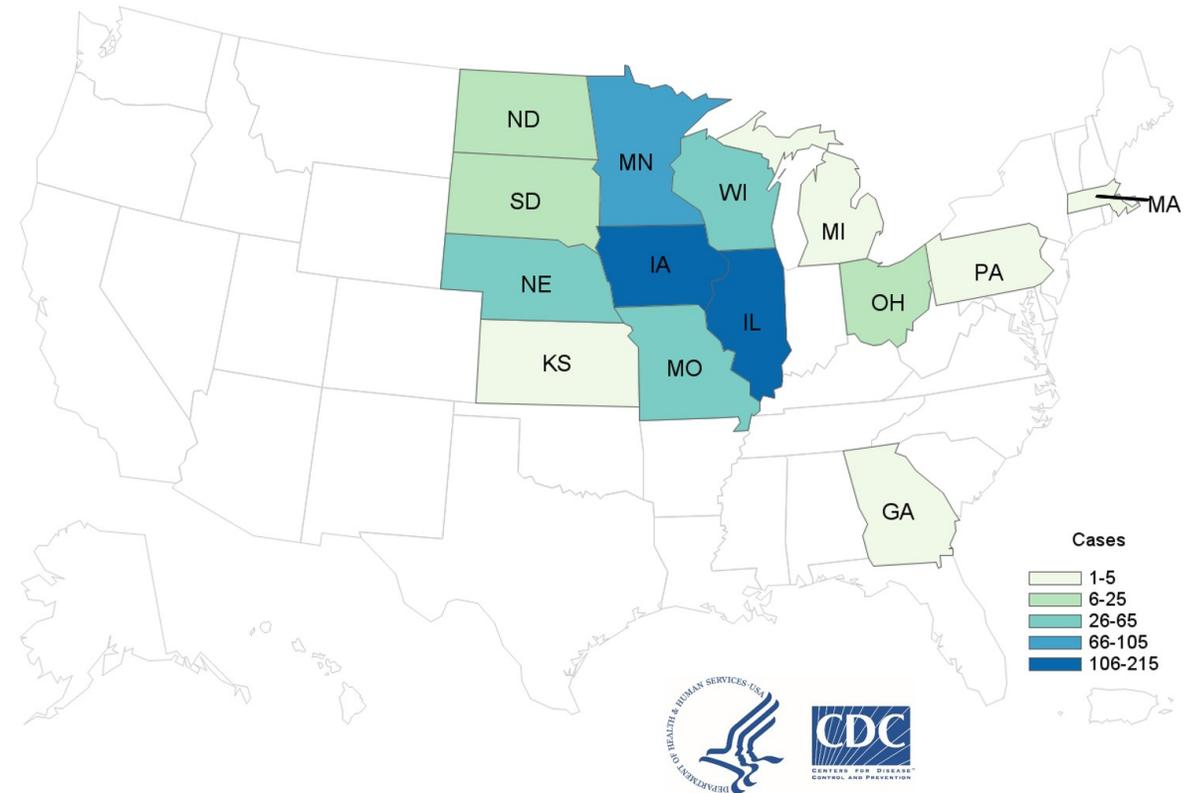
- On June 19, 2020, The U.S. Food and Drug Administration (FDA), along with the Centers for Disease Control and Prevention (CDC), and state and local partners, announced an investigation into a multistate outbreak of *Cyclospora* illnesses.
- The outbreak was potentially linked to three private label grocery store Garden Salad mixes containing iceberg lettuce, red cabbage, and carrots.



Bagged Salad Outbreak Epidemiology



- Total Illnesses: 701
- Hospitalizations: 38
- Deaths: 0
- Illness Onset Date Range: 5/11/2020 – 7/24/2020
- Outbreak declared over: 9/25/2020



Source: CDC.gov

Traceback

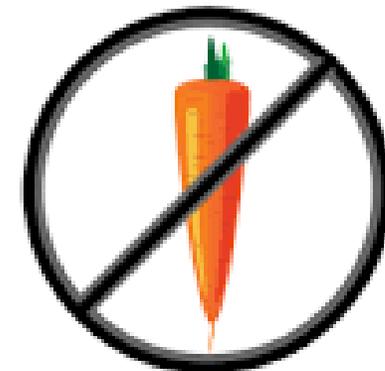


- Traceback was initiated on four private label pre-packaged salad products.
- All salads contained three ingredients:
 - Iceberg lettuce
 - Red cabbage
 - Carrots



Traceback

- Traceback revealed that product distributed to store locations reported by case patients, during the timeframe of interest were manufactured by Fresh Express at their Streamwood, IL, processing facility.
- Based on the traceback, carrots were ruled out as the possible contaminated ingredient.
- The cause or source of the outbreak has not been determined.



Recalls

- On June 27, 2020, Fresh Express recalled products containing either iceberg lettuce, red cabbage or carrots and displaying the product code Z178, or a lower number. The “Best by” date on the products ran through July 14, 2020.
- This recall expanded earlier recalls conducted by grocery store chains.



Fresh Express Streamwood Inspection



- Traceback identified the Fresh Express Streamwood, IL, processing facility as the common manufacturer.
- FDA initiated an inspection at this facility and collected multiple product and water samples.
- All samples were negative for *Cyclospora*.





California Farm Investigations



- FDA investigated multiple farms identified via traceback.
- FDA investigations took place in California including two farms, a farm crew, and a cooler.
- Environmental and product sampling occurred in the farms in California.
 - All samples were negative for *Cyclospora*.



Florida Canal Sample

- FDA analyzed water samples from two public access points along a regional water management canal (C-23), located west of Port St. Lucie, FL.
- Given the emerging nature of genetic typing methodologies for this parasite, the FDA has been unable to determine if the *Cyclospora* detected in the canal is a genetic match to the clinical cases, therefore, there is currently not enough evidence to determine the cause of this outbreak.
- Samples were analyzed utilizing validated method BAM 19c – Dead End Ultra Filtration (DEUF).



Next Steps

- While the source of the outbreak remains unknown, the presence of *Cyclospora* in a canal that had previously supplied irrigation water in the region, and specifically to a farm identified in the traceback, suggests the need for a collaborative effort by state, federal and industry partners to better define the scope of the contamination and identify appropriate risk mitigation measures.

Cyclospora Prevention

- FDA continues to update BAM 19b with additional produce items as validation occurs. Updates are posted to the web.
- FDA works to educate growers both domestically and internationally on *Cyclospora*.
- Subtyping methodologies for both clinical and product samples are in development.

Conclusion

- *Cyclospora* outbreaks are complex.
- FDA, CDC, and state partners continue to work together to identify the source of outbreaks caused by *Cyclospora*.
- Further research is needed and is ongoing.
- FDA and partners continue to work on mitigation strategies as new information is learned.