

Fresh Express 2018 Cyclospora cayetanensis outbreak Summary and Response

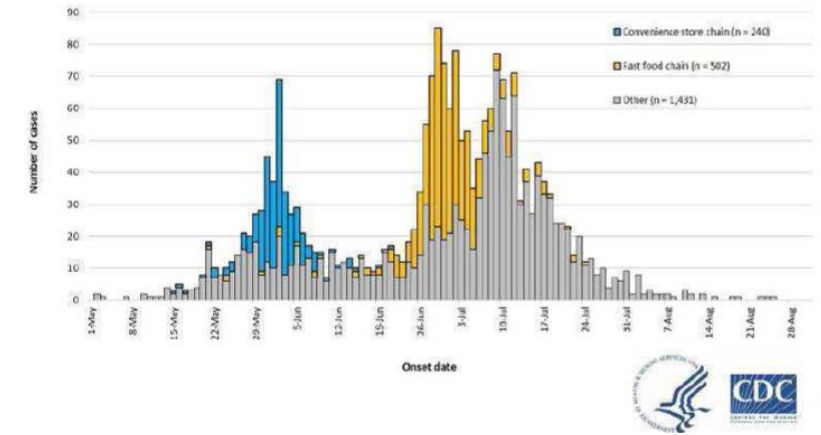
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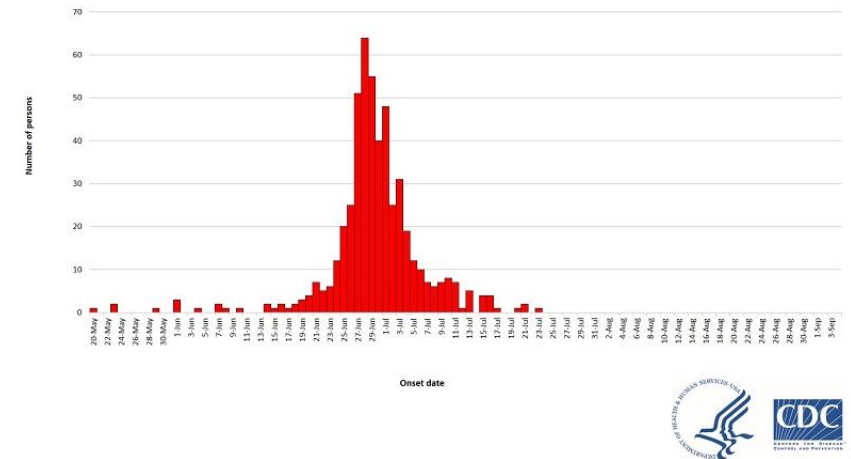
Fresh Express

Summary

- In the spring and summer of 2018, Fresh Express and other fresh produce suppliers were linked to a *Cyclospora cayentanensis* outbreak — with U.S.-grown fresh produce samples testing positive for the parasite
- 2299 lab-confirmed patients were reported to the CDC by 33 States. All these people had no history of international travel.
- 761 of these cases were connected to two outbreaks associated with Fresh Produce, and the specific sources of contamination for the remaining cases were not determined.
- Fresh Express was implicated with the Mc Donald's Outbreak infecting 511 people



People who reportedly consumed salads from McDonald's and were infected with *Cyclospora*, as of September 11, 2018 (n=511)*.



2018 Fresh Express Cyclospora Event Summary

- May –July: 511 confirmed McDonald's cases in 15 states
- May –Aug: Nationally, 2,299 confirmed cases in 33 states
- July 13th: McDonald's stopped selling salads from FEX Facility
- July 26th: FDA sample of Romaine/carrot blend found positive
- July 27th: FEX initiates product recall
- August : FDA two positive samples in raw Romaine –CA
- Sept 11th: Outbreak declared to be over
- FDA investigations did not identify a point of contamination
- FEX field investigations did not identify a point(s) of contamination
- FEX plant investigation did not identify any non-conformances

Traceback results

- 330 cases had Romaine (1 case no reference to Romaine)
- 89 cases with no consumption information
- Date of harvest 6/2 to 6/18/2018
- No Romaine lot, block or grower was 100% associated
 - 219 cases (66%) had romaine from Ranch A
 - 188 cases (57%) had romaine from Ranch B
 - 213 cases (64.5%) had romaine from Ranch C
 - 89 cases (27%) had romaine from Ranch D
 - 152 cases (46%) had romaine from Ranch E
 - 93 cases (28%) had romaine from two different ranches in Central Mexico
 - Multiple sub-lots from most ranches above
- Harvest crew analysis did not show any significant commonality of crews
- Therefore, is Cyclospora more prevalent than what we thought?

Fresh Express Action Taken in Response to Cyclospora at Facility

- The trim and pack out lines that produced the Romaine and Carrot Blend which tested positive for Cyclospora were:
 - Removed from service
 - Disassembled, full tear-down
 - Deep cleaned
 - Sanitized
- Both the trim and pack out lines food contact surfaces (Zone 1) were tested for Listeria and Cyclospora.
- All Listeria and Cyclospora tests results were negative.
- FDA and California Dept of Health visited all three suppliers involved with the Cyclospora positive sample.

Fresh Express Preventive Action Plan Harvest Crew Improvements

- New pair of gloves
 - At beginning of day
 - Any time after someone goes into the restroom
 - After every break and lunch
- Rotator Position: Observation of hand washing & Sanitary Facilities
 - Rotator will make sure that everyone washes their hands at the beginning of the day and after each break. Check sanitary facilities for proper maintenance
- Glove dipping stations
 - Before entering field employees must dip their gloves in a container with germicide abilities
 - Proper documentation and record keeping should be kept of the solution throughout the day
- All Employees and visitors must walk through a created path, this prevents unintentional stepping on the product prior to harvest
- In 2019 begin transitioning all hand washing station to be hands free on portable restroom units

Industry Collaboration

- Sharing of historic experience with specific Cyclospora GAPs and programs
- Open access to available Cyclospora-specific sampling and test methods
- Unprecedented sharing of test results and historic learnings
- Informal risk monitoring and alert communications between willing industry contributors

Cyclospora Blue Ribbon Panel Formed

- **Inaugural meeting occurred in Nov, 2018**
- **Food Safety experts unite against industry Cyclospora Concern**
- Panel Chair: Dr. Michael Osterholm –leading epidemiologist and infectious disease expert
- Panel was comprised of scientist with deep expertise in the biology of the Cyclospora cayetanensis organism, food safety, outbreak response and public health (including expert observers from the FDA, CDC, USDA, and CDPH).
- Four groups formed: Root cause assessment, prevention controls, collaboration and testing validation
- Interim report contains the preliminary findings, recommendation and on-going prioritize of the four working groups. Report also contains fact sheet that outlines the illness, symptoms, testing methods and ways for all handlers to reduce the risk of contamination and useful resources.
- **Overall goal:** Gain great understanding of Cyclospora and develop potential mitigation strategies for the entire industry.

Fresh Express Response to the Event

- Focus on human interactions, fecal matter disposal and water quality/contamination
- Increased awareness of cyclospora in the FEX field food safety program including a focus and improvements with harvest crew training, portable toilet facility improvements, rotating monitor, etc.
- Closer scrutiny of actual and potential flooding events and location of potential sources of human waste including septic systems in residential, municipal and other sources such as RV parks
- Monitoring of clinical cases through the CDC website and a hospital in Central Mexico in the growing region monitoring the health of the general population and potential farm workers. Increase our efforts when we start to see significant increases in clinical cases

Fresh Express Report Response to the Event (cont.)

- Pre-harvest surveillance testing in products sourced from Mexico and romaine in U.S.
 - Yuma, AZ over 100 samples
 - Huron, Ca 110 samples
 - Salinas, Ca 137 samples
 - Central Mexico 263 samples
- Support of research projects to survey agricultural and environmental water for *Cyclospora*
- Continued *collaboration* with industry partners and regulatory agencies to develop knowledge, research needs and potential mitigation actions

Next Steps

- Review and interpret findings to identify action items (if any)
- Revisit Blue Ribbon Panel for recommendation on next phase – e.g. water assessment if validated method is determined or other(s)
- Conduct a gap analysis related to potential exposure of fields to human waste (i.e. scrutinize portable toilet practices)
- Implementation of action items (i.e. if any) to further reduce risk associated with toilets, etc.

Accessing the Preliminary BRP Report and Fact Sheet

- Fresh Express - <https://www.freshexpress.com/blue-ribbon-panel-report>
- Product Marketing Association- <https://www.pma.com/content/press-releases/2019/interim-report>
- United Fresh Produce Association - <https://www.unitedfresh.org/additional-resources/>