

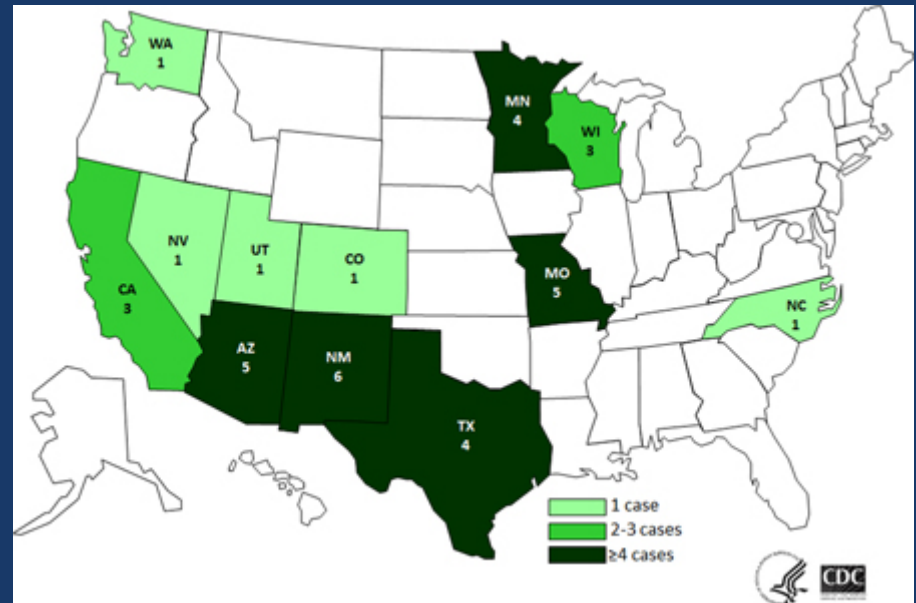


Listeria monocytogenes outbreak Associated with Caramel Apples

2015 InFORM Conference

Listeria monocytogenes /Caramel Apples Coordinated National Response

- ★ First reported outbreak associated with whole apples coordinated by CORE
- ★ 35 cases reported from 12 states
 - 4 of 5 FDA Regions involved
- ★ 2 cases reported in Canada
 - One with reported Caramel Apple consumption

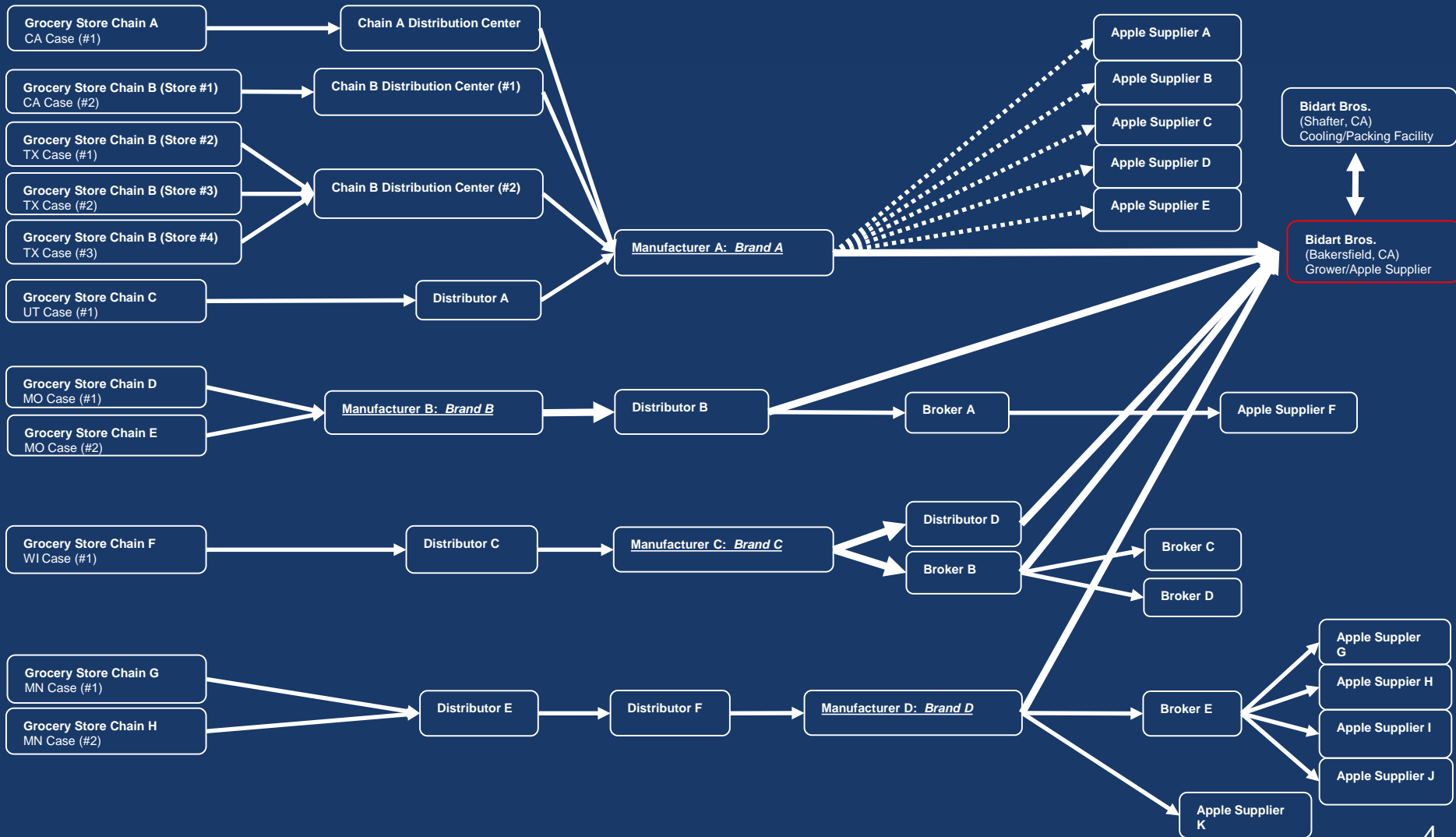


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- **11/21/14**
 - ★ FDA CORE Signals began evaluating 2 clusters of *Listeria Monocytogenes*
- **12/15/14 – 12/16/14**
 - ★ CDC: 9/9 cases reported caramel apple consumption
- **12/18/14**
 - ★ Inspections at firms initiated
- **12/22/14**
 - ★ First of numerous voluntary recalls initiated

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• Inspectional Observations

★ Caramel Apple Production

- Mostly Seasonal
- Granny Smith Apples
- Commercially Processed
- Potential processing issues
- Smaller apples

★ Caramel Apple Distribution

- Nationwide



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- Environmental and Product samples
 - ★ Sampling conducted at multiple points along distribution chain
 - ★ Samples from Bidart facility are PFGE and WGS match to clinical cases



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- Recalls

- ★ Bidart Bros. Granny Smith and Gala Apples

- December 22, December 24, January 6

- ★ Multiple Caramel Apple manufacturers

- Happy Apple Company of Washington, Missouri
- California Snack Foods, of El Monte, California
- Merb's Candies of St. Louis, Missouri

- ★ Canadian recalls



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Next Steps

1. Implicated product removed from market
2. FDA will continue to work with Industry
3. Transition to Post Response/Prevention



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Prevention Efforts

- Outbreak strain found in supplier and manufacturing environment
- Federal and Non-Federal entities continue to conduct studies
 - ★ Whole unprocessed apples vs. caramel apples
- Upcoming FDA assignments to determine how caramel apples processing environment may contribute to a contaminated product

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- Conducted at the Institute for Food Safety and Health | Illinois Institute of Technology | Moffett Campus
- Characterized the behavior of LM in caramel and fresh apples
- Findings:
 - ★ LM survived but did not grow on fresh apples
 - ★ Growth significant for caramel apples if contamination at the stick end
 - ★ Growth in caramel apples was slower at 5°C than at 25°C
 - ★ Both low and high level contamination resulted in approx 10^{11} pathogen cells per apple
- Submitted for publication in Journal of Food Protection

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Upcoming FDA Assignment Purpose

- To observe and document practices that may increase the risk of *L. monocytogenes* introduction, growth, or contamination in caramel apples
- To provide and give insight into the prevalence of *L. monocytogenes* in the environment and how contamination occurs
- To develop strategies for reducing the environmental contamination

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Upcoming FDA Assignment Objectives

- Conduct GMP inspections of firms that produce caramel apples as identified
- Collect and analyze environmental samples at each firm
- Collect evidence necessary to support the appropriate regulatory action when significant violations are observed.
- Upon confirmation of *L. monocytogenes* positive samples from environmental sampling, determine if *L. monocytogenes* is linked to reported outbreaks utilizing whole genome sequencing (WGS)

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Success factors

- Professionals dedicated to promoting public health
 - Astute epidemiological work to identify vehicle
 - Prompt federal and local response
 - Prevention efforts in progress