

FDA *Cyclospora*: Collaborating with Iowa/Nebraska

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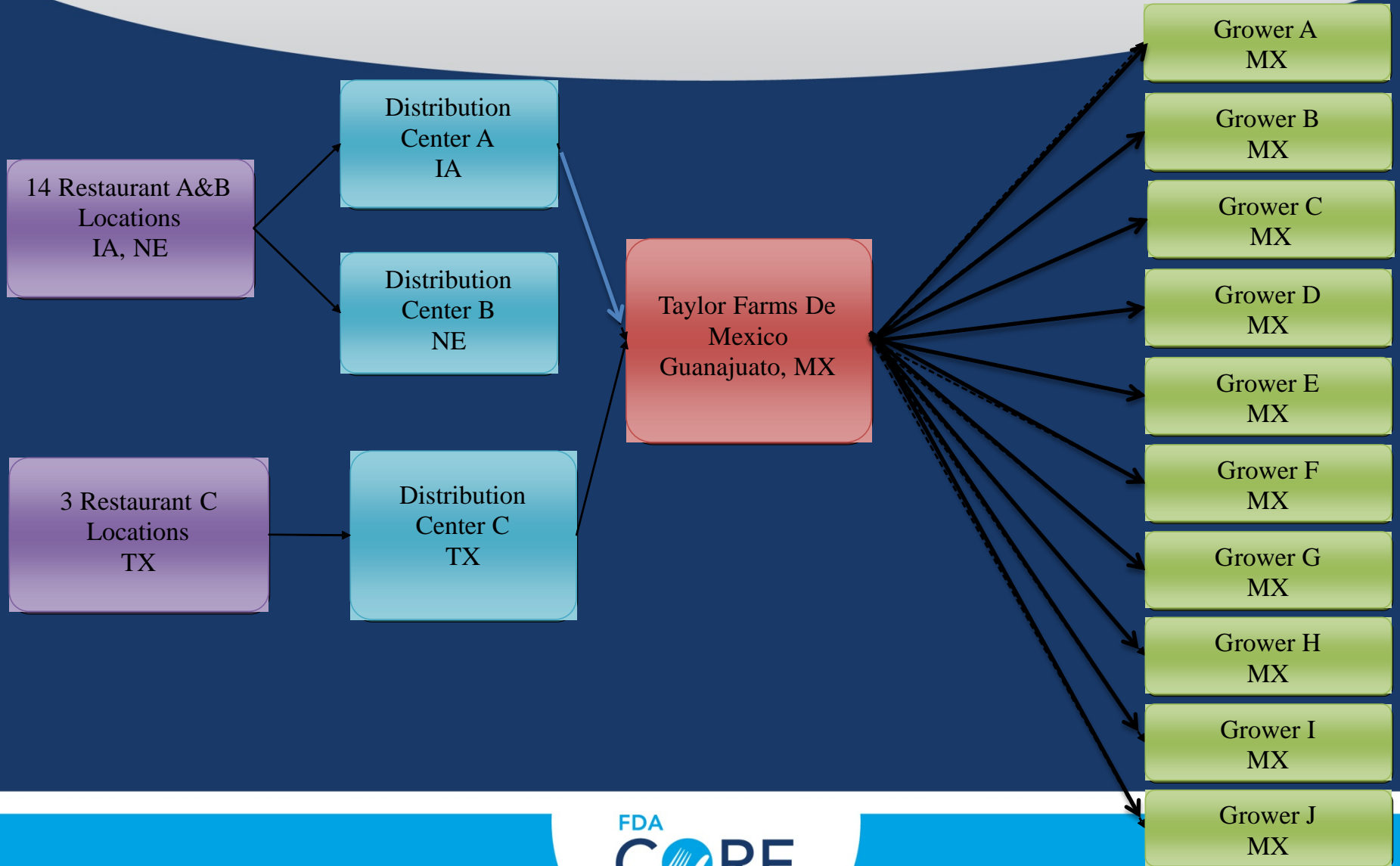
InFORM 2013

San Antonio, TX

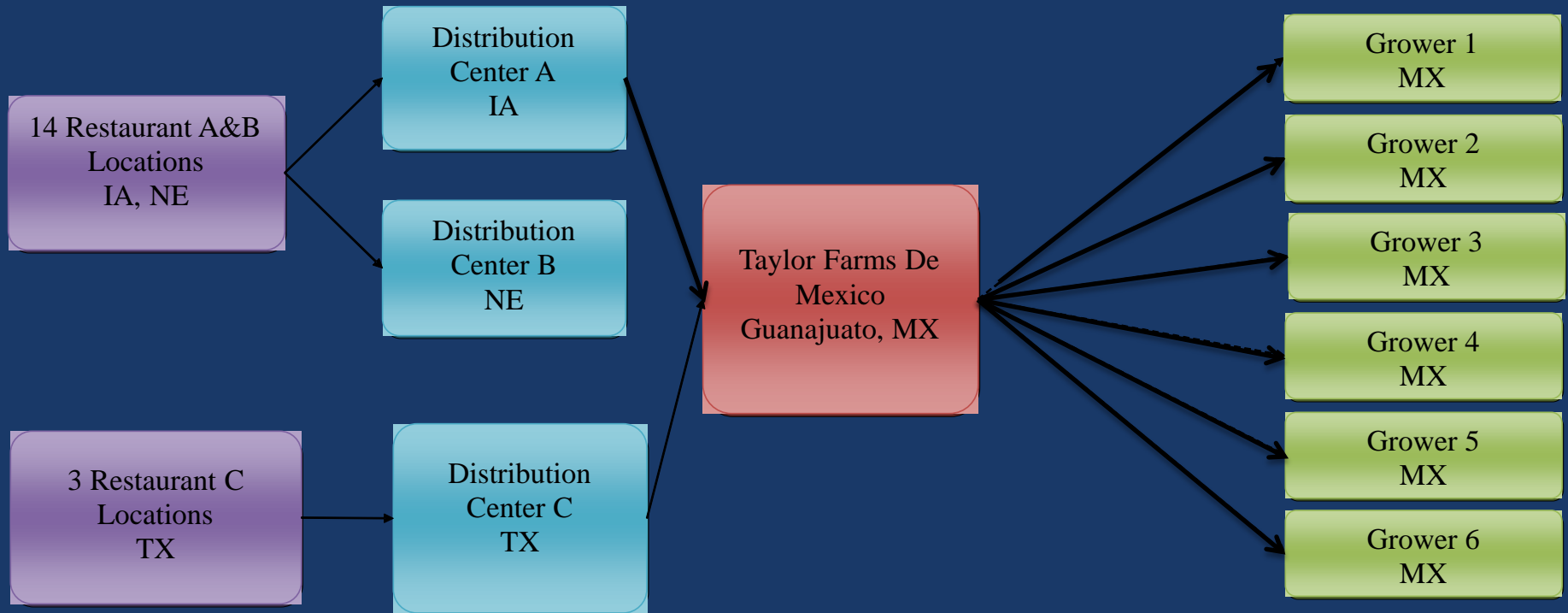
Timeline of Events

- CORE begins evaluating a cluster of *Cyclospora* cases in Iowa on July 4.
- July 30- Iowa and Nebraska announce bagged salad mix as the source of *Cyclospora* infections
- August 9- Taylor Farms de Mexico voluntarily suspends production and shipment of any salad mix, leafy green, or salad mix components
- August 11-19- A team of investigators from FDA, CDC, Mexico, and Taylor Farms perform an environmental assessment

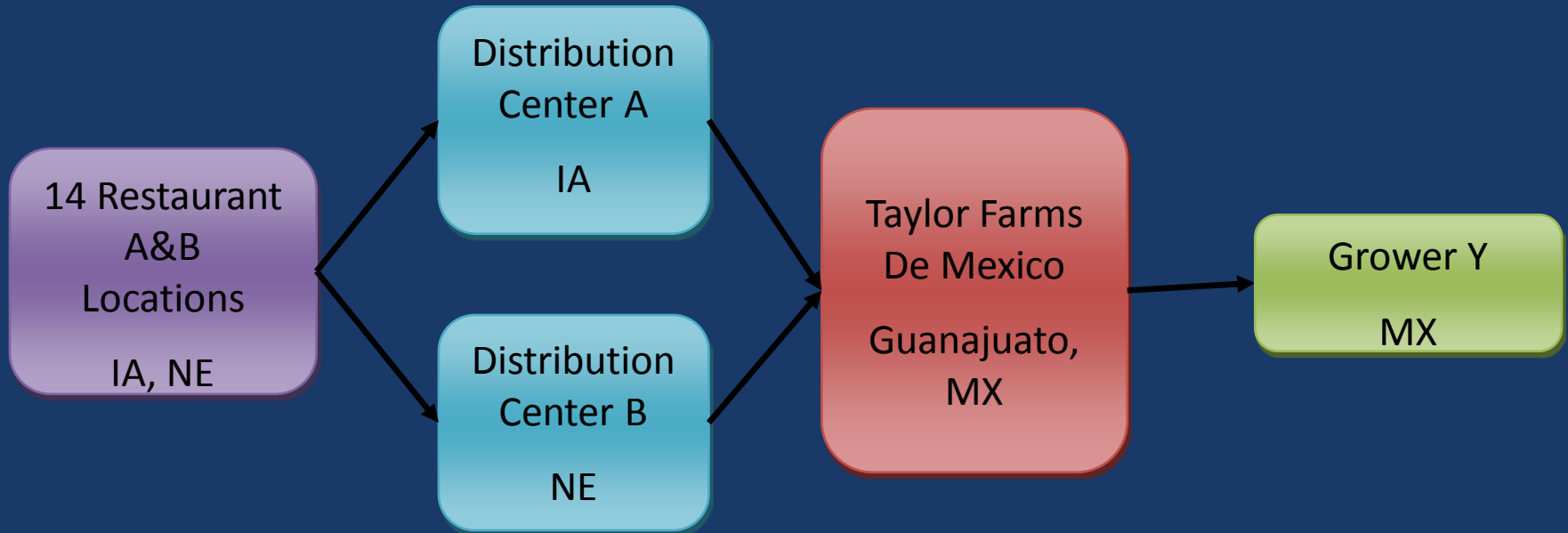
Traceback of Iceberg Lettuce



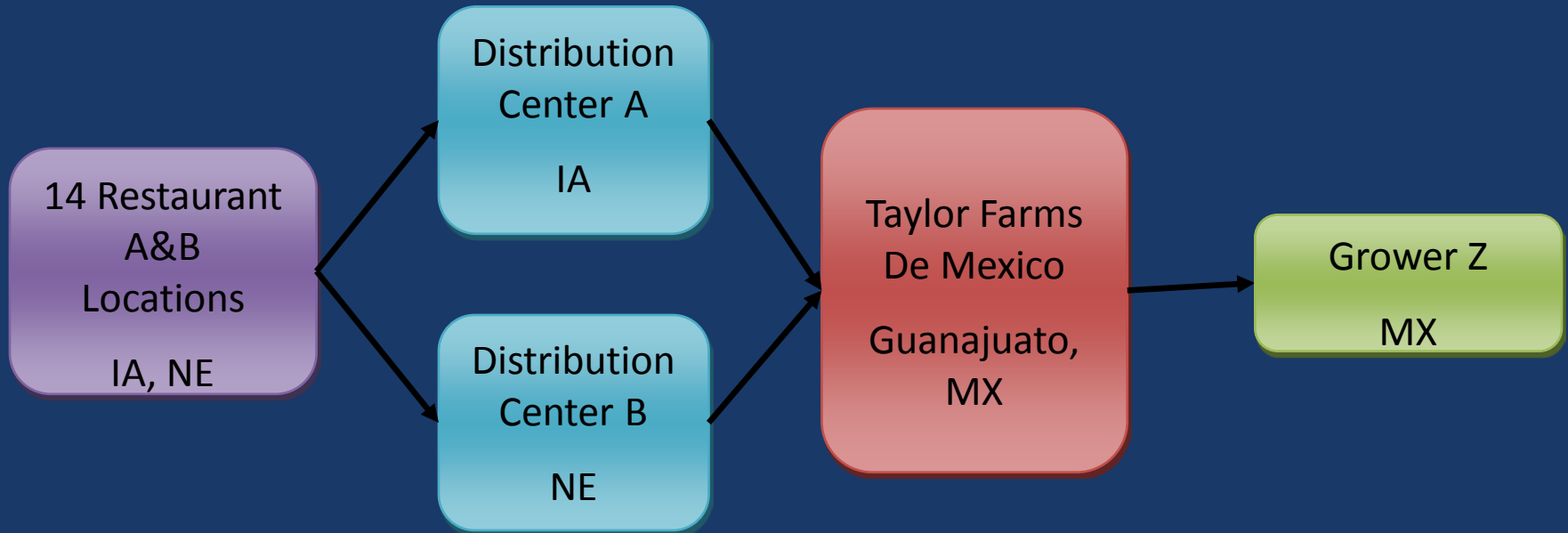
Traceback of Romaine Lettuce



Traceback of Red Cabbage



Traceback of Carrots



Environmental Assessment

- Grower locations to be assessed were determined based on traceback data
 - ★ Priority was given to growers that supplied a majority of the iceberg lettuce in the bagged salad mix component
 - Iceberg was the only ingredient in common to cases with Restaurant C exposure in TX
 - ★ Growing locations were also determined based on common lots supplying salad mix
 - Red Cabbage supplier was sole supplier of red cabbage
- Carrot supplier was common, but geographical distance prevented a visit from the EA team

EA: Results

- The EA Team assessed the following locations:
 - ★ 4 leafy green ranches
 - ★ 1 red cabbage ranch
 - ★ 1 processing facility (Taylor Farms de Mexico)
- All samples collected by FDA, CDC, and Taylor Farms were negative for *Cyclospora*
- The EA Team did not identify any significant potential sources of the outbreak pathogen, or any significant potential contamination routes at any of the locations visited

EA: Recommendations

- Perform an EA of the carrot ranch located in Sonora, Mexico
- Recommend research to determine if *Cyclospora* is reasonably likely to be a food safety hazard in the Guanajuato, MX leafy green growing region
- Encourage ill employees that receive anti-diarrheal drugs and broad spectrum antibiotics to submit stool samples for *Cyclospora* testing
- Establish procedures for the hand wash facilities to facilitate the control, reduction, and elimination of human pathogens from employee hands, by evaluating the worker hygiene facilities to maximize accessibility and use, while minimizing the potential for the facility to serve a source of contamination.

Conclusions

- FDA has not been able to definitively determine how or at what point in the supply chain *Cyclospora* may have contaminated the salad mix associated with the outbreak
- Taylor Farms resumed production of bagged salad mix products on August 25, 2013
- FDA continues to assist the state of Nebraska on their in depth record review

FDA *Cyclospora*: Collaborating with Texas

LCDR Kari Irvin

CORE Response Team 3 Lead

InFORM 2013

San Antonio, TX

Two Outbreaks

- How did TX, CDC, and FDA determine this?
 - ★ A detailed look at the epi curve
 - ★ Exposure data from TX cases
 - Including information from various clusters
 - ★ Product traceback
 - Change in product type- shredded lettuce exposure vs. whole head lettuce
 - Change in product origin- Lettuce from MX vs. lettuce from USA

Epi Curve: IA/NE vs. TX

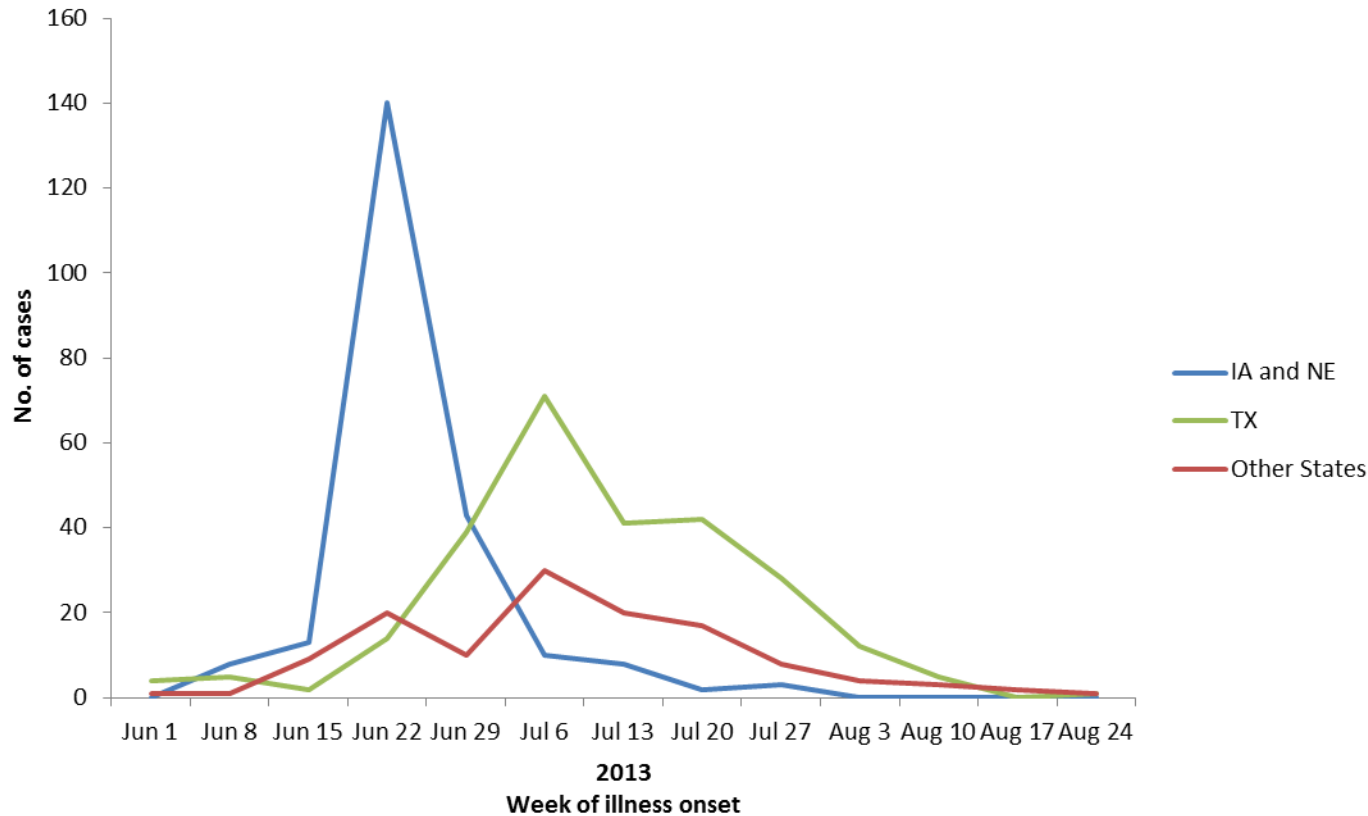
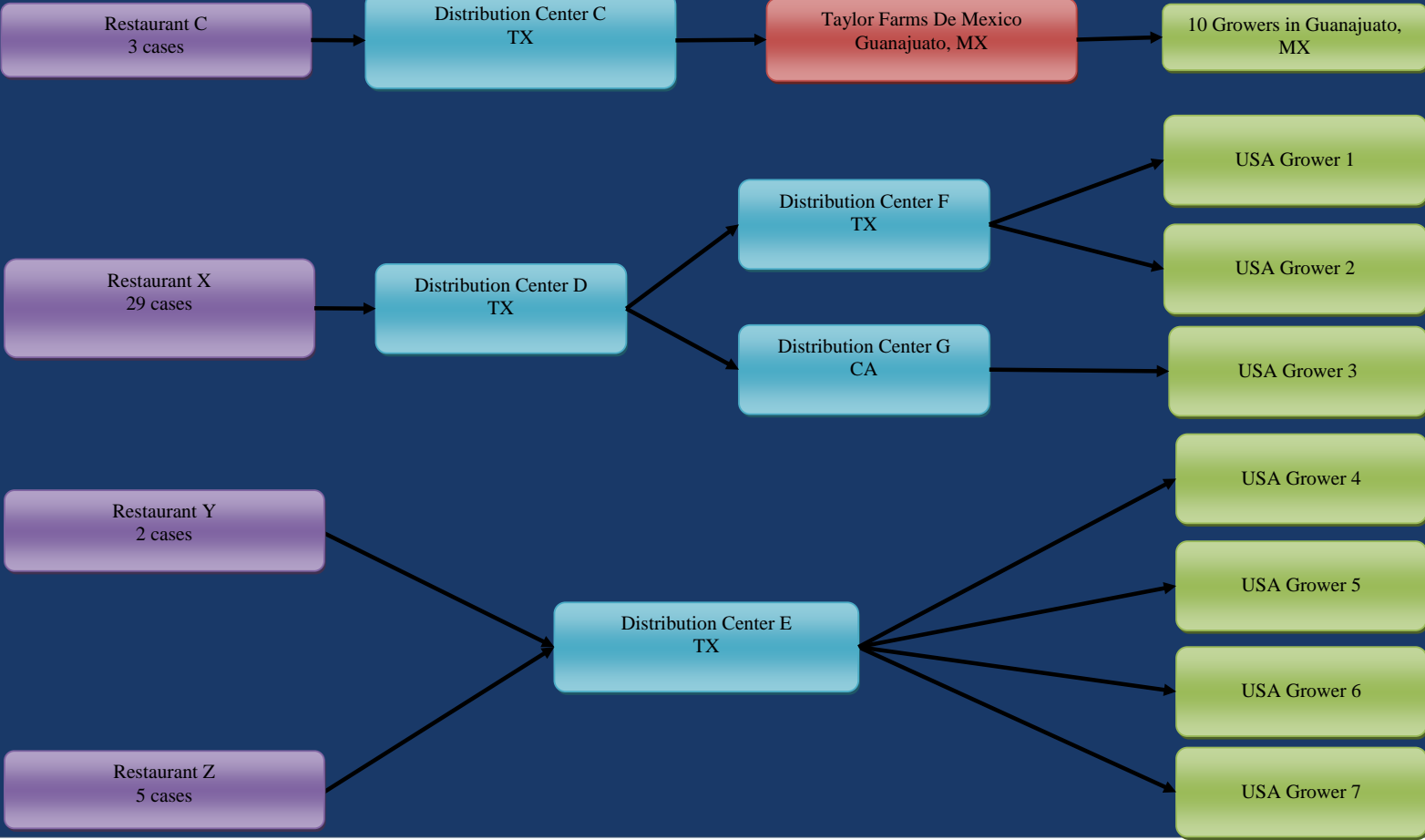
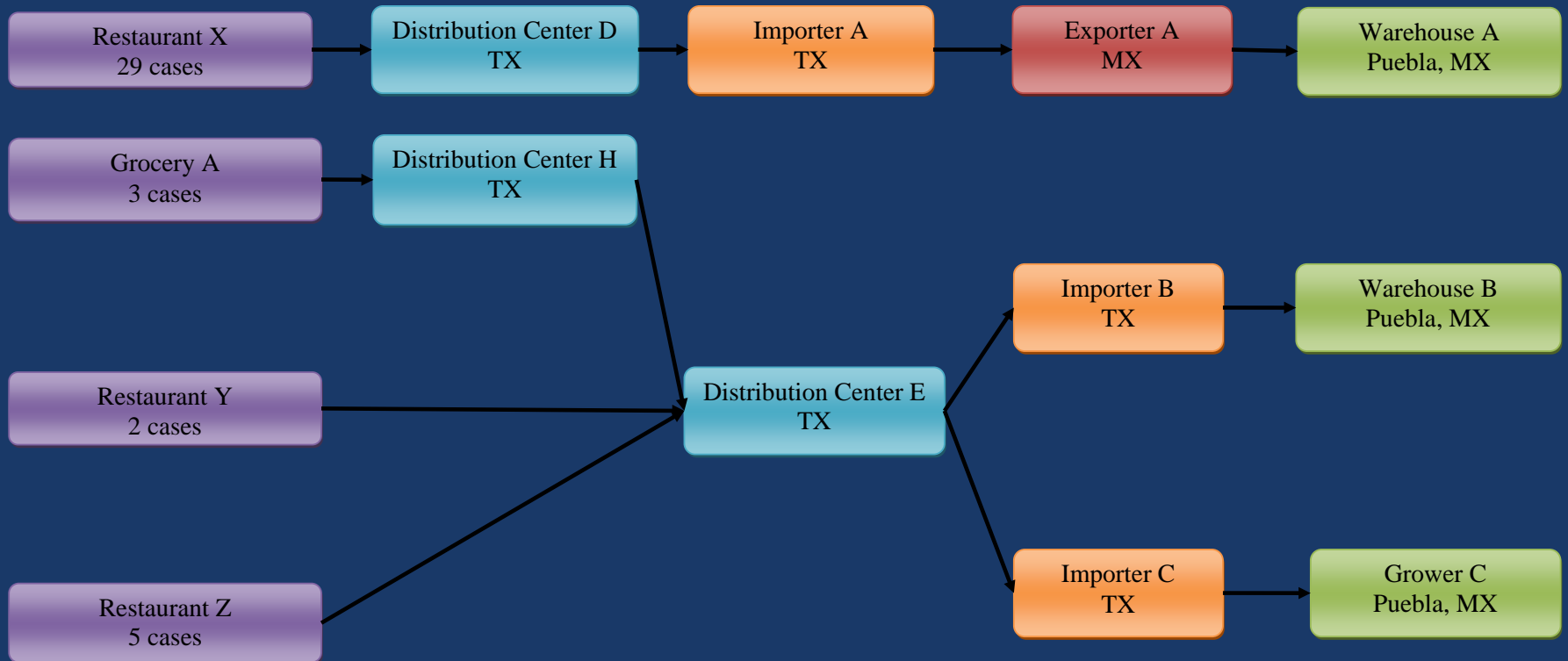


FIGURE. Laboratory-confirmed cyclosporiasis cases by week of onset — United States, June 1-September 10, 2013
Courtesy of CDC

Iceberg Lettuce and TX Restaurant Clusters



Cilantro and TX Restaurant Clusters



Ongoing Activities

- FDA continues to work with our partners in Mexico to determine:
 - ★ Conditions of the firms identified in the cilantro traceback located in Puebla, MX
 - ★ If there is a common cilantro farm that supplied the warehouses identified in the traceback
- Based on information received from these follow-up investigations, FDA will consider potential action/follow-up at the firms

Challenge #1: *Cyclospora* and Laboratory Methods

- Level of surveillance in other countries
- Lack of genetic typing methods for *Cyclospora*
 - ★ Can we determine clusters for traceback?
 - ★ Increase in time it takes to relate cases to the outbreak
 - What might be background?
 - What product was the case exposed to?
- Product Testing Methods
 - ★ Improvements needed on methods to detect *Cyclospora* in leafy greens and other commodities

Challenge #2: Traceback

- Poor record keeping at point of service locations
 - ★ Undocumented purchases at local grocery stores
 - ★ Product inventory interviews and record review don't tell the same story
 - ★ Cash and carry shipments
- Determining clusters
 - ★ So many cases should= many restaurant clusters, right?
 - Cases had multiple restaurants in common with others, so a single point of service of interest was difficult to identify at times

Challenge #3: Communications

- While federal/state communications during outbreak responses continues to improve, CORE is aware that issues still exist
- The complex nature of this outbreak highlighted several areas for improvement:
 - ★ Public messaging
 - ★ Data sharing- must be a two way street
 - ★ Challenges with Disclosing Confidential, Commercial Information

Conclusions

- FDA continues to perform *Cyclospora* surveillance sampling on cilantro supplied by the firms of interest
- FDA will work with industry to discuss strategies on preventing *Cyclospora* contamination in fresh produce items
- CORE continues to work with federal and state partners to improve our coordination role in future outbreaks

Acknowledgements

- All state partners
 - ★ IA, NE, TX, and WI
- CDC
- Government Authorities in Mexico
- Taylor Farms

Cyclospora Feedback

- We welcome your feedback and recommendations!
- If you were part of the *Cyclospora* investigation and want to provide a recommendation, please complete our online survey:
 - ★ <https://www.surveymonkey.com/s/3C6NN7V>