U.S. FOOD & DRUG ADMINISTRATION

FDA CORE NETWORK | COORDINATED OUTBREAK RESPONSE & EVALUATION

CORE Overview

2016 Review

June 18, 2017

What is CORE?

- FDA's Coordinated Outbreak Response and Evaluation Network
- Manages Surveillance, Response, and Prevention activities related to incidents of illness linked to FDA-regulated human food, cosmetics, and dietary supplements
- Designed to streamline and strengthen FDA's efforts to:
  - Detect
  - Investigate
  - Respond
  - Evaluate
  - Apply Lessons Learned

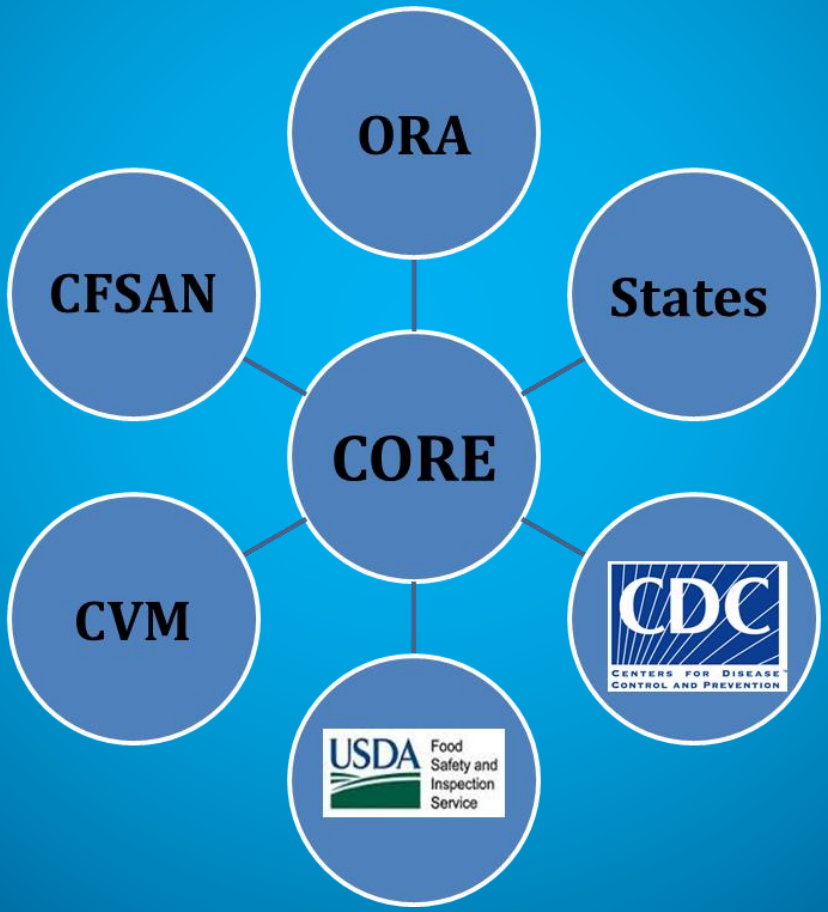
CORE's Goals

- Streamline outbreak-related processes
- Enhance transparency and working relationships with our internal and external partners
- Communicate with state and federal partners throughout incidents

CORE's Scope

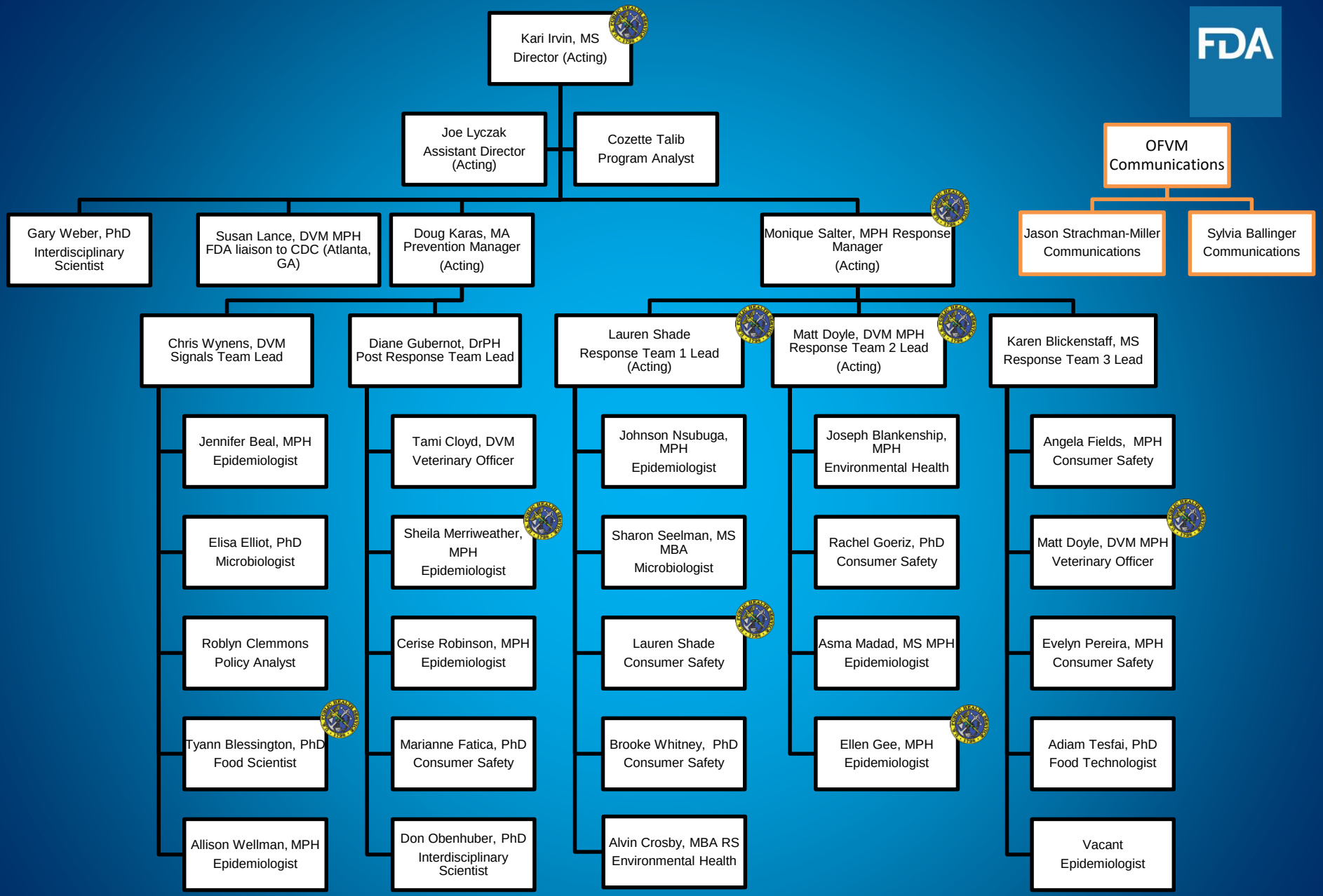
- Evaluating early epi investigations of clusters or illnesses
- Coordinating complex outbreak response activities across CFSAN, ORA, the States and CDC
- Responding to outbreaks where an in-depth investigation is needed
- Determining prevention efforts based on outbreak data trends and findings
- Ensuring implementation of lessons learned into preventive strategies to minimize future public health threats

The CORE Network



CORE's Functional Areas

- Signals and Surveillance
- Response
- Post-Response
- Communications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CORE Signals and Surveillance

- Analyzes internal and external information for illness trends and potential clusters of illness
- Evaluates emerging clusters of illness
- Communicates regularly with CDC and USDA to discuss emerging human and animal food outbreaks
- Provides data and trending information for situational awareness reports

CORE Response

- Coordinates information flow across organizations during a response including the States and CDC
- Along with ORA, others in FDA, the States, and CDC, determines strategy for and manages the implementation of response activities
- Conducts traceback investigations in collaboration with FDA District Offices
- Evaluates environmental, epidemiologic, and laboratory data to inform assignments and outbreak investigations
- Applies ICS principles during response efforts

CORE Post-Response

- Engages with other FDA Centers and Program Offices
- Conducts reviews of outbreak responses and develops reports to improve subsequent efforts
- Contributes to the development of FDA guidance, policies, and regulations
- Recommends prevention initiatives based on trends of outbreak data and lessons learned
- Maintains the CORE Outbreak Database and provides outbreak-related data

CORE Communications

- Ensures consistent and coordinated messaging during outbreaks
- Develops talking points, FAQs, and web copy
- Participates on inter-agency workgroups to enhance outbreak communications efforts with CDC and USDA
- Works with internal and external stakeholders

CORE's Mission from 2011-2016

- Find outbreaks: >575 Evaluations
- Stop outbreaks: 156 Responses
- Prevent outbreaks: >650 Recommendations

CORE Network Response 2016

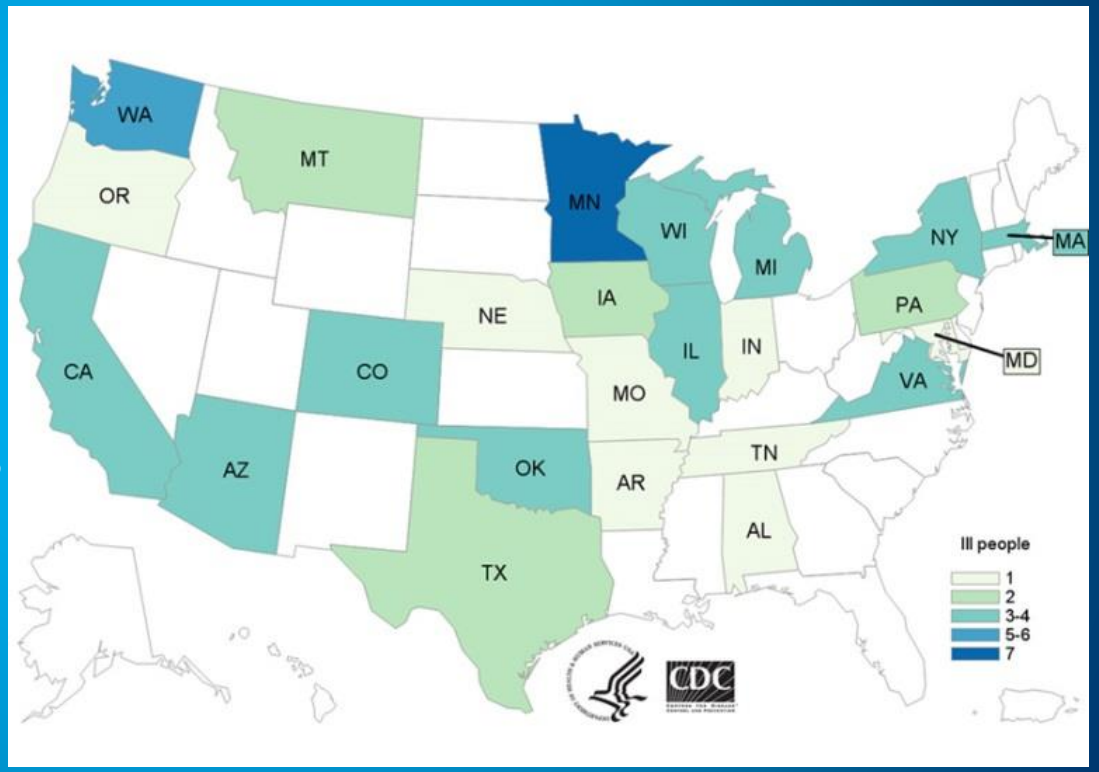
- Total number of Incidents : 22
  - *Salmonella* spp: 11
  - *Listeria monocytogenes*: 5
  - *E.coli* : 3
  - Hepatitis A: 2
  - Other: 1
- Total Number of Traceback Investigations: 16
- Assignments Issued: 42
- Samples Collected and Analyzed: 304

CORE Network Response 2016

- Product Actions
  - Import Alerts: 7
  - Increased Import Surveillance: 6
  - Recalls: 37
  - Market Withdrawal: 7
- CORE Communications posted 64 web pages/updates
- Post Response received 237 recommendations from 22 incidents transferred to them

2016 multistate outbreak of *E.coli* O121 and O26 associated with flour

- Case Count: 63
- States: 24
- No deaths
- 1 HUS
- 17 hospitalizations
- Onset Dates: 12/21/15 – 9/5/16
- Age range: 1-95 years; median 18
- Two serotypes: O121 and O26
- Main serotype: *E. coli* O121:H19
- Five PFGE patterns associated



Initial Information

- February 2016: PulseNet starts tracking a small cluster of STEC O121:H19 infection with an unusual PFGE type

- Initial signals for the cluster were identified as romaine lettuce, broccoli, and beef. CDC later notified FDA of a signal for home bakers who mentioned exposure to the same of brand flour and raw cookie dough.

- Seven cases were selected for an initial informational traceback investigation and six were exposed to flour manufactured at a single manufacturing facility in Kansas City, MO;
  - five of these six cases were exposed to flour manufactured within an eight day timeframe.
  - State and FDA samples of flour were collected and analyzed for E. coli O121.
  - Five state-collected samples were positive for the outbreak strain.

Traceback – the power of convergence

Timeline

- Epidemiologic Signals point to flour
- Raw dough exposure at restaurants noted.
- Flour supplier and likely manufacture dates ascertained – recall initiated 5/31/16
- Positive product sample confirmed by FDA
- Positive product sample confirmed by FDA outside of recall bracket. Recall expanded 7/1/16
- Firm proactively tests flour samples and expands recall on 7/25/16

In Summary

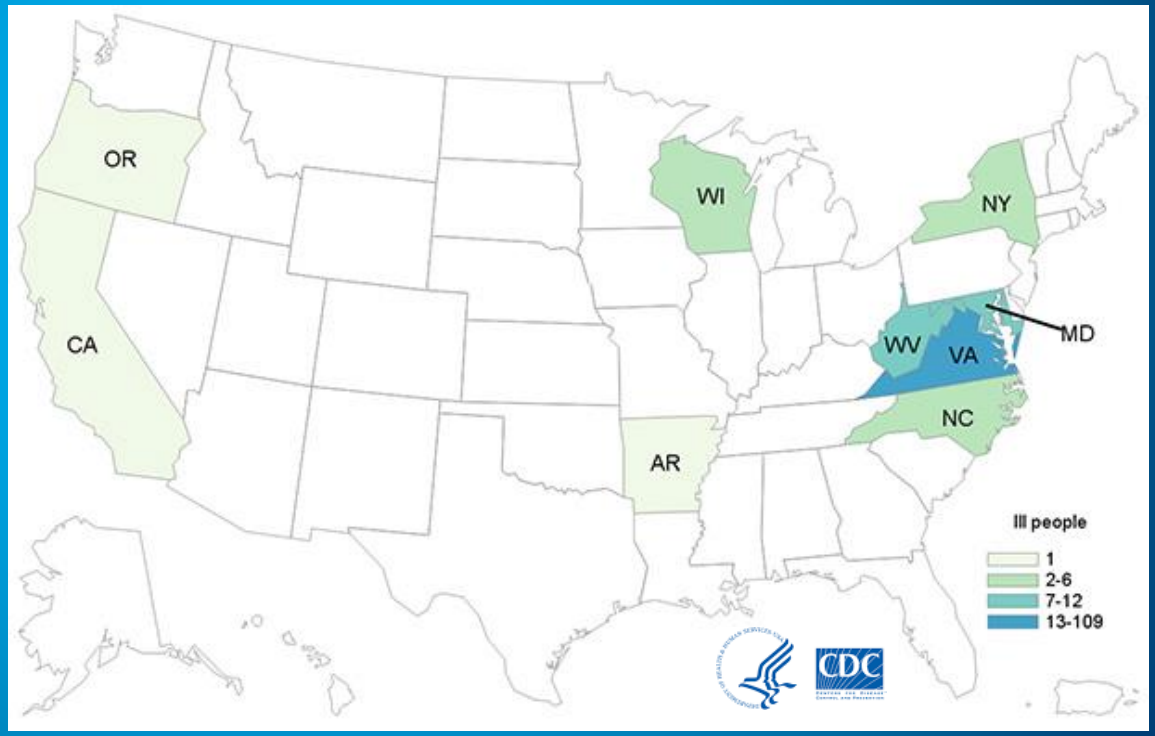
- Convergence of epidemiologic, informational traceback, and microbiological analyses
- Dough or raw flour has been suspected before for STEC
  - 2009: 80 cases *E. coli* O157: Commercial raw cookie dough
  - 2012-3: 35 cases *E. coli* O121: Frozen food products
  - 2016: 13 cases *E. coli* O157: Dry dough mix for dessert pizza
- First time flour was confirmed as a vehicle in an outbreak
- Communication among FDA, CDC, and their respective laboratories was instrumental in successful product testing
- Multiple recalls associated with this outbreak
- **Flour is not considered a ready-to-eat food**

Acknowledgements
E.coli in flour

- State Partners
  - California Department of Public Health
  - Colorado Department of Public Health and Environment
  - Maryland Department of Health and Mental Hygiene
  - Minnesota Department of Health
  - Virginia Department of Agriculture and Consumer Services
  - Washington State Department of Health
- Center for Disease Control and Prevention
- FDA/ORA District Partners
  - Minneapolis
  - Kansas City
  - Denver
  - Dallas
  - Detroit
  - Florida
  - Seattle
  - San Francisco
- FDA/CFSAN
  - Office of Food Safety
  - Office of Regulatory Science
  - Office of Compliance
  - Office of Analytics and Outreach
- FDA/OFVM Communications staff
- Pacific Regional Laboratory, Northwest

2016 multistate outbreak of Hepatitis A associated with frozen Egyptian strawberries.

- 143 cases in 9 states
- 56 hospitalized
- 0 deaths



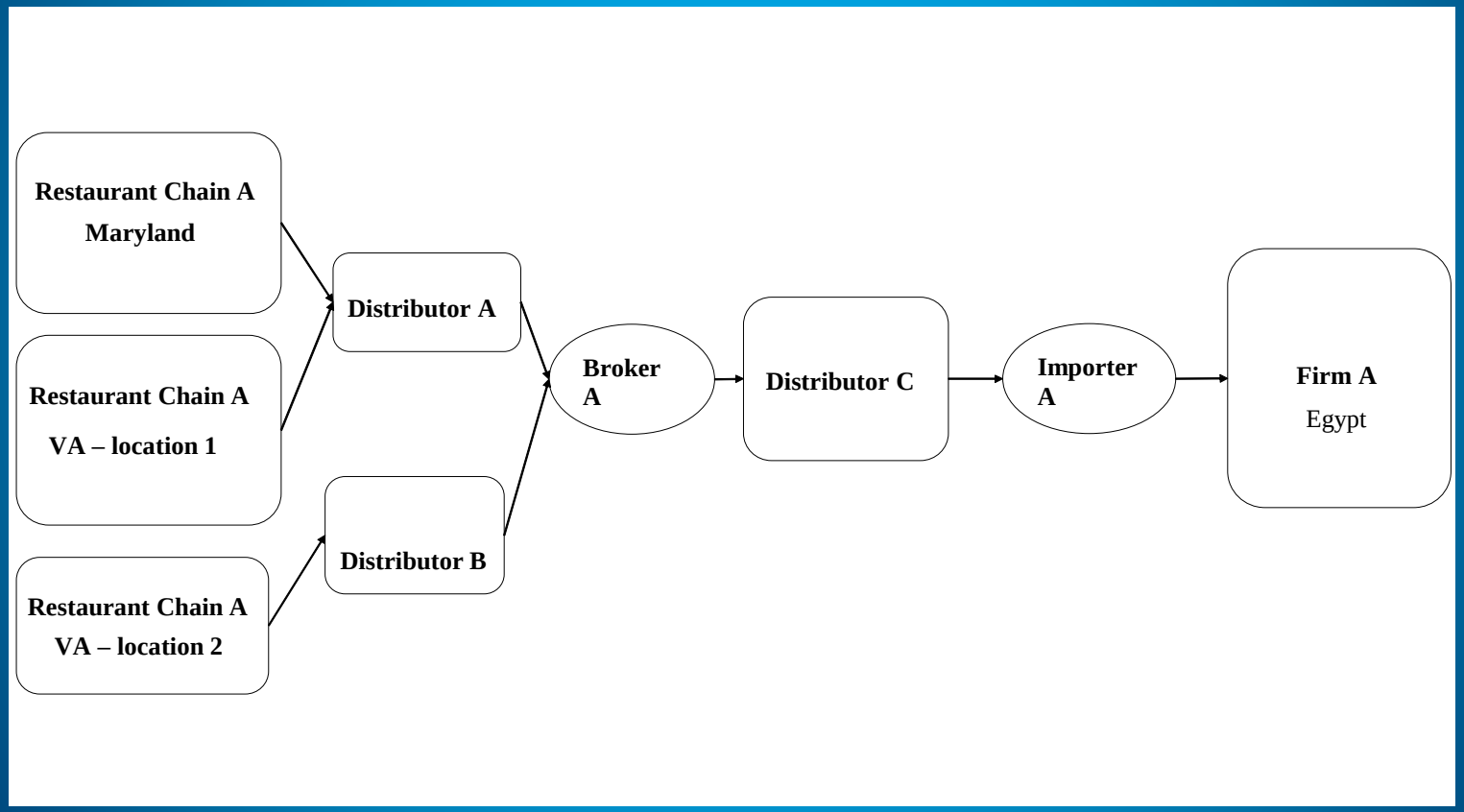
Initial Information

- **August 2016**: CORE Signals was notified through a CDC Epi-X about Virginia Department of Health (VDH) investigation of acute hepatitis A infections
  - There were seven cases of non-travel associated illnesses in VA
  - Four clinical isolates were genotyped as hepatitis A 1b

- Case patient food histories indicated exposures to smoothies containing frozen strawberries consumed at the same restaurant chain.

- Early during the investigation, VA RRT collected epidemiologic information and conducted an informational traceback that identified Egyptian frozen strawberries served at the restaurant locations as the suspect vehicle.

Strawberries Identified



Successes and Challenges along the way……

Product Action - Challenges

- Domestic distributor referred recall question to Importer A (corporate office in Canada)
- Importer A referred recall to Egyptian firm
- Difficulties speaking with Egyptian firm until they hired a US attorney

Product Action - Success

- Restaurant Chain stopped using Egyptian frozen strawberries (8/8/16).
- Domestic distributor voluntarily placed strawberries on hold (8/15/16).
- Egyptian firm placed on Import Alert 10/19/16
- Egyptian firm recalled all product 10/25/16

Successes and Challenges along the way……

Laboratory

- HAV 1b strain isolated from 6/19 samples (32%).
- Preliminary screen and confirmatory testing conducted in separate laboratories

Communications

- Concern that recall was not be effectuated. FDA released the names of the 5 direct consignees of the Egyptian firm.
- Quick information sharing was critical due to Post-Exposure Prophylaxis (PEP) window.

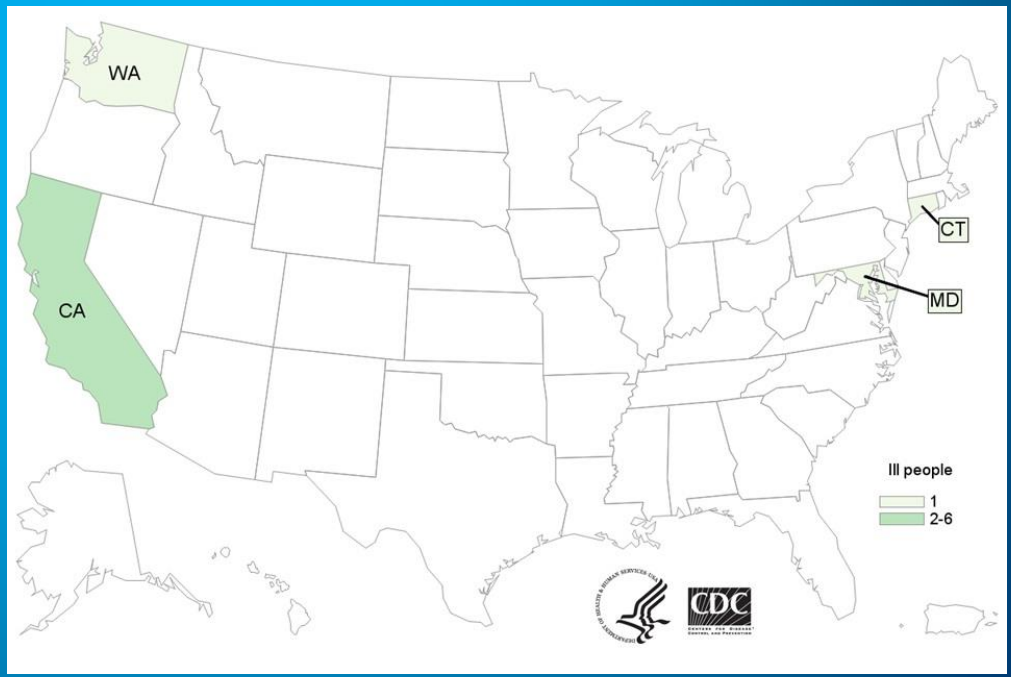
Acknowledgements

Hepatitis A in frozen strawberries

- **State Partners**
  - California Department of Public Health, California Food Emergency Response Team (CalFERT), Maryland Rapid Response Team, Michigan Department of Agriculture and Rural Development, New York City Department of Health and Mental Hygiene, New York State Department of Health, Virginia Department of Agriculture and Consumer Services, Virginia Department of Health, Virginia Rapid Response Team, West Virginia Department of Health and Human Resources, Wisconsin Department of Agriculture, Trade and Consumer Protection, Wisconsin Department of Health Services
- **Centers for Disease Control and Prevention**
  - Division of Viral Hepatitis, Division of Foodborne, Waterborne, and Environmental Diseases; Outbreak Response and Prevention Branch
- **Canadian Food Inspection Agency**
- **Public Health Agency of Canada**
- **FDA/ORA District Partners**
  - Baltimore, Atlanta, Minneapolis, New York, Dallas, Los Angeles, Chicago, New Jersey, Kansas City, Detroit
- **FDA/ORA Headquarters**
  - Office of Regulatory Science, Division of Import Operations, Office of Food and Feed Program Operations, International Programs, Office of Enforcement and Import Operations. Office of Operations
- **FDA/OFVM Communications staff**
- **FDA Laboratories**
  - Southeast Regional Laboratory, San Francisco Laboratory, Pacific Regional Southwest Lab, Winchester Engineering and Analytic Center , Gulf Coast Seafood Laboratory
- **FDA/CFSAN**
  - Office of Food Safety, Office of Applied Research and Safety Assessment, Office of Compliance, Office of Analytics and Outreach, International Affairs Staff, Division of Produce Safety

2016 multistate outbreak of *Listeria monocytogenes* associated with frozen vegetables

- 9 cases; 4 states
- Isolation dates: 9/13/2013 – 5/3/2016
- Case-patient age range: 56-91years; median age: 76 years
- 9 hospitalized, 3 deaths
- Two different rare PFGE patterns



Retrospective outbreak

Whole Genome Sequencing identified a link between clinical cases and product and environmental samples from two different firms.

- 3/8-9/2016: 2 environmental & 2 product samples collected at first firm (Firm A) by FDA Seattle District Office.
  - 19/105 environmental subsamples found positive for LM
  - 2 were linked to clinical isolates by PFGE/WGS

- 4/11/2016: frozen corn and frozen peas from second firm (Firm B) collected at retail by OH Department of Agriculture
  - Both positive for LM; PFGE/WGS match to primary outbreak and secondary outbreak patterns

Product Actions

- 4/6/2016 – Firm A voluntarily recalled wholesale onion products based on laboratory and available epidemiologic information
- 4/8/2016 – Firm A expanded recall
- 4/23/2016 – Firm B issued a recall frozen vegetable products based on results Ohio state sampling (11 products)
- 5/2/2016 – Firm B expanded recall to include all organic and traditional frozen vegetable and fruit products processed/packed since 5/1/2014 (42 brands)
- FDA facilitated the recall of over 450 products related to this outbreak.

Outcomes

- Product voluntarily removed from market
- Both firms temporarily ceased operations to address issues noted during investigation
- 7/15/2016: Warning letter issued to Firm A

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Acknowledgements

Listeria monocytogenes in Frozen Vegetables

- **State Partners**
  - California
  - Connecticut
  - Maryland
  - Ohio
  - Virginia
  - Washington
- Centers for Disease Control and Prevention
  - Division of Foodborne, Waterborne, and Environmental Diseases; Outbreak Response and Prevention Branch
- **FDA/ORA District Partners**
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- **FDA/CFSAN**
  - Office of Food Safety, Office of Regulatory Science, Office of Compliance, Office of Analytics and Outreach, International Affairs Staff,

2017……..

- ***Listeria monocytogenes* outbreak linked to Creamery in New York.**
  - 8 cases in 4 states
  - An open consumer sample was collected and tested by the Connecticut Department of Public Health. The sample was later identified as coming from a specific creamery in New York.
  - Outbreak strain was recovered from the consumer sample, retail samples, and cheese sampled at the creamery
  - As a result of the investigation, all cheeses from the creamery were recalled

- ***E.coli* O157:H7 outbreak linked to soy nut butter.**
  - 32 illnesses in 12 states
  - Epidemiologic, laboratory, and traceback evidence identified soy nut butter as the likely source.
  - The firm initiated a voluntary recall of select lots of products, which was followed by a larger, expanded recall which included all lots.
  - FDA suspended the Food Facility Registration for the contract manufacturer of the soy nut butter products.


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