FDA’s Foodborne Outbreak Response

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Topics

• CORE Background
• Outbreak investigations involving State samples
• *Salmonella* Concord in imported tahini
Role of FDA in Foodborne Outbreak Investigations

- Traceback of suspected foods to their source
- Food and environmental testing
- Communications – Public, internal, congressional
- Product and regulatory actions
- Environmental assessments of farm or production facilities
- Regulations and guidance to prevent outbreaks
CORE

- Coordinated Outbreak Response and Evaluation (CORE) Network
- Launched August 1, 2011, and currently includes seven multidisciplinary teams
- Created to coordinate FDA’s activities
  - Signal Evaluation/Surveillance
  - Response (three teams)
  - Outbreak Evaluation
  - Outbreak Analytics
  - Communications
- Outbreaks due to FDA-regulated food, dietary supplements, and cosmetics
Incident Movement Through CORE

Signals → Response Team 1 → Outbreak Evaluation → Outbreak Analytics
→ Response Team 2
→ Response Team 3

Communications

Types of evidence gathered at each stage
- Epidemiologic Data
- Product Traceback
- Historic Data Trending
- Historic Laboratory Data
- Inspectional Laboratory Data
- Predictive Data Analysis
- Investigational Finding at Firm
- Risk Modeling

Vehicle Status (Ideally at each stage)
- Unknown → Suspect → Confirmed
How is a Food Implicated in an Outbreak?

Three types of information used:

- **Epidemiologic:** association between illness and food exposure

- **Traceback:** suspected food item links back to a common source of contamination

- **Microbiologic/laboratory:** pathogen found in the food, farm or facility
WGS and The Changing Face of Foodborne Outbreaks

- Replaces PFGE as primary molecular characterization
- FDA uses WGS to identify links between FDA product or environmental isolates and clinical isolates
  - *Listeria monocytogenes*, STECs, and *Salmonella*
  - Routine and dynamic comparisons between sequences of food/environmental isolates and sequences for clinical isolates
- FDA performs WGS on all foodborne pathogen isolates from FDA samples

Use of WGS for foodborne outbreak detection and response should result in:
- Identification of more clusters, smaller case counts
- Shift in temporal boundaries of an outbreak (longer range)
- Greater clarity of relationships between isolates
- Improved targeting of resources
- Enhanced foodborne illness attribution
- More retrospective outbreak investigations

WGS is one of many pieces of the outbreak puzzle
Challenges for WGS use in Foodborne Illness Outbreak Investigations

Integration
- Transition from PFGE to WGS in outbreak procedures
- Historical comparison

Interpretation
- How close is close enough?
- What does relatedness mean?

Prioritization
- How do we triage clusters for investigation?
- What is our new baseline/background?

Communication
- How do we communicate WGS results to different audiences (firms, lawyers, publicly)?
Role of States in Foodborne Outbreak Investigations

- Multiple state and local agencies are involved in foodborne outbreak investigations: Health, Agriculture & Environmental Health Departments, Public Health Laboratories
- States (and localities) detect and respond to localized foodborne outbreaks and collaborate with federal agencies during national investigations
- States complete WGS of food, environmental, and clinical isolates
- Participate in PulseNet and (in some cases) Genome Trakr
Investigations that involved State samples

- *Salmonella* linked to papayas (2017)
- *Listeria monocytogenes* linked to soft cheese (2017)
- *E. coli* O26 in flour (2019)
- *Salmonella* linked to tahini (2019)
- *E. coli* O157:H7 linked to romaine from Salinas, California (2019)
- Scombroidotoxin fish poisoning linked to tuna (2019)
Salmonella Concord in imported tahini
Initial Epidemiology

- Four cases in 3 states (MA, NY, TX)
- Onset dates: 3/11/19 to 3/25/19
- Age range: 8 to 32 years (median: 21.5 years)
- NYC cases indicated a signal for tahini, tahini-containing foods, and Mediterranean-style foods (hummus, falafel)

4/16/19
CORE Signals notified; First State sample collected

4/22/19
Incident transferred to CORE Response
Traceback & Sampling

POS A
Texas

POS B
New York

POS C
New York

Distributor A
New York

Importer A
FL

Foreign firm A
(Nablus, West Bank)

Negative State sample

Positive State sample
Product Actions

- FDA held a firm call with the importer on 5/6/19. Importer ceases distribution.
- Importer initiated a recall of retail and bulk tahini imported between the dates of December 2018 to January 2019 on 5/15/19.
  - Expanded recall on 5/17/19 to include all tahini products, including those imported prior to December 2018 and until the final shipment in April 2019.
  - Expanded recall on 5/20/19 to include specialty brand tahini sold in 135-ounce containers.
  - Expanded recall on 6/10/19 to include 106-ounce (3-kg) buckets of tahini.
- International Food Safety Authorities Network (INFOSAN) notification issued to inform international partners.
Enforcement Actions

• On 5/30/19, Foreign Firm A was added to Import Alert 99-19 for products that appear to be adulterated due to the presence of *Salmonella*, which allows the FDA to detain products without physical examination.

• Foreign Supplier Verification Program (FSVP) inspection initiated and closed out on 5/17/19. A FDA 483a was issued.
  – Warning Letter issued
  – Importer was the first firm added to **Import Alert #99-41, Detention without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the FSVP Regulation.**
Final Epidemiology

- Six cases in 3 states (MA, NY, TX)
- Onset dates: 3/9/19 to 5/2/19
- Age range: 8 to 33 years (median: 21 years)
- One hospitalization
- Four of 6 people interviewed reported eating tahini or tahini containing foods in the week before becoming ill

Timeline:

- 4/16/19: CORE Signals notified; First State sample collected
- 5/3/19: State sample reported positive
- 5/15/19: Importer A initiates recall
- 5/17/19: FSVP inspection initiated
- 5/30/19: Foreign Firm A added to IA
- 6/26/19: Outbreak over
Lessons Learned

- FDA concurrence with state sample analysis
- International engagement
- FSVP inspections during outbreak investigations