Impact of Traceability During Foodborne Illness Outbreaks

Karen Blickenstaff
Response Staff Director, Coordinated Outbreak Response and Evaluation Network (CORE), FDA CFSAN

Laura Gieraltowski
Lead, Foodborne Outbreak Response Team, Outbreak Response and Prevention Branch, Division of Foodborne, Waterborne and Environmental Diseases, Centers for Disease Control and Prevention (CDC)
Coordinated Outbreak and Response Evaluation (CORE) Network

• 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
• Coordinating complex outbreak response activities across FDA, the States and CDC
• Responding to outbreaks where an in-depth investigation is needed
Federal Roles

• CDC:
  – Disease surveillance
  – Outbreak detection and investigation
  – Education and training of public health staff

• FDA & FSIS:
  – Food safety policies
  – Inspection and enforcement
  – Product recall and traceback
  – Investigation of farm and production facilities

Problem identification
Source implication

Risk assessment and management
Source assessment
Epidemiologic Data Collection Challenges

- Ill people interviewed 2-4 weeks after illness onset
- Commonly eaten foods such as leafy greens, chicken, and beef
- New foods may not be routinely asked about
- Stealthy ingredients such as onions, peppers, and spices
- Lack of brand/product information for produce and chicken and beef
- Identifying sub-clusters is critical
Outbreak Case Study: Multistate Outbreak of *Salmonella* Newport Infections Linked to Onions

- 1,127 ill people (24% hospitalized, 0 deaths) from 48 states
- Utilized illness sub-cluster investigations to identify vehicle
  - Ingredients, like onions, difficult to implicate with patient recall alone
  - Early findings showed 9/9 sub-clusters served red onions
  - Utilized restaurant and other invoices to identify which red onions were supplied
- Single, common onion grower identified by FDA
- Traceback evidence led to the company voluntarily recalling onions starting on August 1, 3 weeks after the outbreak first detected
- Due to the way onions were grown and harvested, red, yellow, and white onion varieties were recalled
Outbreak Case Study:
Multistate Outbreak of Salmonella Newport Infections Linked to Onions

• Investigation Challenges
  — Difficult to identify the source when contaminated item is in a wide range of foods and is commonly eaten
  — Difficult to trace back and recall the many items affected and to provide easy public guidance

• Lessons Learned
  — Rapidly interviewing ill people to identify sub-clusters was critical
  — Focusing on sub-cluster investigations and traceback are a highly effective way of solving ingredient-driven outbreaks
Outbreak Case Study:
Multistate Outbreak of *Salmonella* Bareilly and *Salmonella* Nchanga Infections Linked to Raw Tuna

- 425 ill people (17% hospitalized, 0 deaths) from 28 states and DC

- Utilized several methods to evaluate the association between tuna and illness
  - A study to estimate the frequency of consumption of tuna among sushi eaters

- Traceback focused on fresh and frozen tuna supplied to 4 sub-cluster restaurants
  - Identified common ingredient used in spicy tuna supplied to all restaurants
  - The common product was a frozen raw nakaoshi scrape yellowfin tuna from a single processing facility in India.
Outbreak Case Study:
Multistate Outbreak of *Salmonella* Bareilly and *Salmonella* Nchanga Infections Linked to Raw Tuna

- **FDA Import Alerts**
  - All fresh and frozen tuna from Company A detained and screened upon entry to the US

- **Product Recall**
  - Company voluntarily recalled frozen raw tuna scrape

- **Advice to the public and retailers**
Traceback Challenges

• An ongoing outbreak; need to act fast
• Poor consumer recollection of consumption history and lack of specific product information
• Multiple product varieties and/or multiple ingredients identified
• Multiple sources of same product at points of sale (POS)
• Poor record-keeping at firms within the distribution chain
• Lack of a rapid and rigorous mechanism to link shipments (or item in a shipment) from farm to fork
• Varying tracing data across the supply chain
Outbreak Case Study:
Multistate Outbreak of *E. coli* O157:H7 Infections Linked to Romaine Lettuce

- Traceback investigation was initiated on 11/18/19 that included 15 points-of-sale (POS)
- Traceback records were requested for all romaine lettuce available to cover the time period of 9/15/19 through 11/18/19
- Lack of lot code traceability for 13/15 POS
  - Took approximately 1 month to collect, analyze and identify growers that supplied the lettuce
  - For the 2 POS where lot codes were available, growers were identified within 24 hours or less
    - Lot codes are not typically available during outbreak situations at POS
- Broad public advisory was issued on 11/22/19
  - Most efficient way to ensure contaminated product was off the market
Outbreak Case Study: Multistate Outbreak of *E. coli* O157:H7 Infections Linked to Romaine Lettuce

Table 1. Traceback Initiation Dates for POS With and Without Available Lot Code Data Associated with *E. coli* O57:H7 Outbreaks Linked to Romaine Lettuce

<table>
<thead>
<tr>
<th></th>
<th>Traceback Initiation Date</th>
<th>Grower Identification Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>POS locations – no lot code data</td>
<td>11/18/19</td>
<td>12/13/19</td>
</tr>
<tr>
<td>MD POS location – lot code data</td>
<td>11/18/19</td>
<td>11/18/19</td>
</tr>
<tr>
<td>WI POS location - lot code data</td>
<td>12/4/19</td>
<td>12/5/19</td>
</tr>
</tbody>
</table>

![Bar chart showing traceback initiation dates for different POS locations with and without lot code data.](chart.png)
Benefits of Better Traceability

• Access to specific KDEs creates efficiencies in the tracing process
  – FDA would likely be able to identify common product sources in
    approximately 5 to 7 days if lot code data is available at POS

• Authorities could have access to information for swifter product
  action

• Opportunity to better scope product actions

• Creates ability to have more refined record requests