ER220
Traceback Investigations

“Train-the-Trainer”
Development Timeline

- Stakeholder Call – Feb. 24, 2012
- 1st Focus Group Meeting – May 10, 2012
  Job Task Analysis (JTA)
  Course Content Review
- 2nd Focus Group Meeting – July 10, 2012
  JTA Verification
  Draft Course Outline
- Report to Stakeholders – August 20, 2012
Job Task Analysis (JTA)
DACUM Chart – Developing A Curriculum

A-1 Develop Project Plan
- A-11 Schedule Farm Visit
- B-1 Conduct Traceback Interviews
- C-1 Conduct Environmental Interviews
- D-1 Implement Bio-Security Procedures
- E-1 Compile Findings

A-2 Develop Traceback Timeline / Flowchart
- A-12 Schedule Farm Visit
- B-2 Conduct Traceback Walk-Through
- C-2 Conduct Firm Walk-Through (process flow)
- D-2 Complete Farm Questionnaire
- E-2 Finalize Flowchart & Timeline

A-3 Identify Immediate Objectives
- A-13 Coordinate Sample Plan (with labs)
- B-3 Document Manufacturing Process Flow
- C-3 Collect Samples (product, environ.)
- D-3 Review On-Farm Food Safety Plan
- E-3 Prepare Compliance Findings

A-4 Assemble Project Team
- A-14 Verify Project Plan
- B-4 Collect Traceback Records
- B-5 Assess Traceback Records
- B-6 Time-Bracketing Implicated Process (receive & ship)
- C-4 Assess Production Records
- C-5 Track Personnel Movement
- C-6 Track Implicated Product Movements

A-5 Coordinate Individual Responsibilities
- A-6 Review Product/Hazard References
- B-7 Time-Bracketing Implicated Process (receive & ship)
- C-7 Track Implicated Product Movements
- D-4 Conduct Additional Interviews
- D-5 Map Possible Contaminant Sources
- D-6 Survey Farm
- D-7 Track Farm Input Movements
- D-8 Track Personnel Movements
- D-9 Track Equipment Movements
- D-10 Verify Sanitation Procedures
- D-11 Evaluate Wildlife / Pest Controls
- D-12 Collect Farm Samples
- E-4 Conduct Firm Closeout Meeting
- E-5 Provide Sample Results (to firm per District policy)
- E-6 Draft Investigation Report
Course Outline

I. Developing the Project Plan
   A. Review Project Assignment – (Background / Incident Package)
      1. Assignment to FDA District Office
      2. Request for Assistance to State/Local Regulatory Partner
         Group Exercise Packet A – First Case Histories
   B. Determine Information Needed
      Group Exercise Packet B – Sample Assignments
   C. Assemble Project Team
      1. Defined Project Team – Engage Various Agencies/Partners/Experts
      2. Review Product/Hazard References
      3. Review Establishment History for Each Firm
      4. Coordinate & Assign Individual Responsibilities – Divide Workload
   D. Logistics* (*as needed)
      1. Develop Safety Plan (if needed)
      2. Determine Project Logistics
      3. Gather Investigation Supplies
      4. Schedule Visit With Firm / Schedule Farm Visit (if appropriate, per protocols)
      5. Coordinate Sampling Plan w/Lab(s) / Identify Shipping Points & Logistics
   E. Verify Project Plan
      1. Share schedules
      2. Exchange/Verify Contact Information
         Group Exercise Packet C – Additional Case Histories
ER220 Traceback Investigations

The First “Train-the-Trainer” Opportunities

Pilot Course: January 29 - February 1, 2013
              Washington, DC
2nd Course:  April 30 - May 3, 2013
              Walnut Creek, CA
3rd Course:  August 6-9, 2013
              Indianapolis, IN
FY14 - "Train-the-Trainer" Continues…

1st Course: January 14-17, 2014
Jacksonville, FL

2nd Course: April 22-25, 2014
Dallas, TX

3rd Course: August 12-15, 2014
Springfield, MA
FY15 – More "Train-the-Trainer"

1st Course: January 2015
Seattle, WA

2nd Course: May 2015
Harrisburg, PA

3rd Course: August 2015
St. Louis, MO
ER220
Traceback Investigations

FY16 – Yet MORE "Train-the-Trainer"

1st Course: January 2016
Richmond, VA

2nd Course: May 2016
Denver, CO

3rd Course: September 2016
Minneapolis, MN
ER220
Traceback Investigations

FY17 – Yet MORE "Train-the-Trainer"

1st Course: January 2016
Los Angeles, CA

2nd Course: May 2016
Memphis, TN

3rd Course: September 2016
Providence, RI
This is YOUR course…

- Make the most of it
- Feel free to ask questions
- Accept the overwhelming
- Network and share experiences
ER220 Course CD

- Agenda & Course Support Documents
- PowerPoints with Speaker Notes
- Exercise Guidance
- Case Study with Actual Traceback (Redacted Records)
- Roster of Participants
Anatomy of an Outbreak investigation

- Disease Surveillance
- Epidemiological investigation
- Laboratory Analysis
- Environmental investigation
- Traceback / traceforward
- Product investigation
What is an FDA Traceback?

- **Documents** the distribution through the supply chain, and the source(s) of a product that has been implicated in a foodborne illness investigation.

**REGULATORY TRACEBACK**
- Collect hard copy records at each firm

**INFORMATIONAL TRACEBACK**
- (“Epi Traceback”)
  - Collect information via phone, email, etc.
### TRACEBACK INVESTIGATION TIMELINE (DRAFT)

<table>
<thead>
<tr>
<th></th>
<th>February</th>
<th>March</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FROM</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smiths, PA, CA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sea One, PA</td>
<td>20</td>
<td>15</td>
</tr>
<tr>
<td>Samuels &amp; Sons, PA</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td><strong>AT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sea One, PA</td>
<td></td>
<td>15</td>
</tr>
<tr>
<td><strong>FROM</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMI Food, CA</td>
<td>20+30</td>
<td>440+484</td>
</tr>
<tr>
<td><strong>AT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMI Food, CA</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FROM</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Her Cheng Fishery Co, Taiwan</td>
<td>7524+2610</td>
<td></td>
</tr>
</tbody>
</table>

DRAFT – Traceback Diagram for Salmonella outbreak. These diagrams contain confidential commercial information intended for FDA use in law enforcement and/or regulatory activities. They may not be further distributed without the written consent of FDA. This diagram is updated as new information is received by FDA-CORE. Revised: mm/dd/yy.
Traceback Investigation

Flow Diagram

POS

Distributors

Packers

Importers/Producers/Farms

Point-of-Service
Date and time food prepared
Date and time food served
Delivery receipt date, time, qty
Stock rotation
Menu and recipes
Food turnover/shelf-life
Inventory
Food product identifiers
Product/Environmental sampling
Ordering practices

Distributors
POS deliveries
Incoming deliveries
Product identifier info/Lot #
Stock rotation
Bill of Lading
AWB
Transportation time

Packers
Distributor deliveries
Incoming deliveries
Product identifier info/Lot #
Stock rotation
Bill of Lading
AWB
Transportation time

Importers/Producers/Farms
Custom Entry Number
Invoice
Bill of Lading
Date of Production
Amount of Product
Production conditions
Lot #
Key Points

● CONFIDENCE
  ● Leadership must have confidence in the trace

● TEAMWORK
  ● Select a leader of the team
  ● need more than one set of eyes on a traceback leg
  ● experienced/trained staff on the traceback team

● DOCUMENTATION
  ● Bills of lading, invoices, etc – more than just Excel spreadsheets from firms
  ● Ownership/Responsibility for collected records
What are the steps?

1. Decide whether to trace or not
   If yes, is it one or more products?
2. Determine clusters to trace
3. Determine the time period to bracket to collect information
4. Collect the information/records, send asap
5. Decipher and analyze
6. Connect the dots / Identify Convergence
Decide what clusters to trace...

Ideally those with:

- 4 or more cases in a cluster, the larger the better
- 3 distinct geographic areas
- Good food historians, and/or key cases with unique histories, and minimal exposures before onset
- Documented food exposure – receipts, shopper card
- Varying types of establishments (groc, restaurant)
- Not complicated with food-handler issues
Traceback Challenges

- Limited Resources (staff, budget, time, etc.)
- Logistics & Support (distance to travel, admin. support, travel limitations)
- Technology Limitations
- Multiple Commodity Responsibilities (regulatory work beyond foods)
- Competing Outbreaks
- Limited Experience (knowledge and/or training in tracebacks)
Traceback Challenges (contd.)

- Ongoing outbreak; need to act fast
- Large numbers of sporadic cases
- Poor consumer recollection of consumption history and lack of specific product information
- Multiple product varieties identified
- Multiple products w/multiple ingredients identified
- Multiple sources of same product at POS
- Lack a rapid and rigorous mechanism to link shipments (or item of in a shipment) from farm to table, factory to fork, boat to throat, etc…
Lack of identifier that connects thru chain.
Leveraging Resources

- Integrated Food Safety System
- FDA Assistance
- Rapid Response Team
- Food Safety Task Force
- Another In-State Agency
- Neighbor State Agency
- Contract 3rd party for certain situations

Establish Contracts, MOU, SOPs before the outbreak hits
Ensure trained staff before outbreak hits
Leveraging Resources (contd.)

- FSMA required product traceability
- Food Shield
- Lab Networks (PulseNet, FoodNet, etc.)
- Palantir Web-Based Dashboard
- Training Exercises
  (ER220, CDC, and other course-in-a-box options)
Important to Remember Industry Role – Engage early!

**Firm(s) involved:**
- Assignments – share why FDA is there
- Provide information and records
- Recall, warn consumers

**Industry Association:**
- Seasonality/sources
- Market patterns
- Distribution patterns
- Assist in getting support from others in industry

**Important to keep industry informed and engaged!**
When to apply options

- Consider each option & when to apply
- Questions that might help decide:
  - Is an investigation likely at that firm?
  - Are samples needed? Are samples possible? Do we just need records and general info?
  - Is there an adverse firm history?
  - Is there info to help narrow which food/ingredient, or do we have an implicated food/ingredient?
  - Is the firm located close to a bordering state?
Summary

- Before the outbreak hits, establish framework to garner resources when needed

- Train ahead and maintain
  - training resources and documents available

- Reach out early; continue communications

*Increase public health protection by leveraging resources*
ER220 Traceback Investigations

Questions?

Allen Gelfius
U.S. Food & Drug Administration
Office of Training, Education & Development (OTED)
Las Vegas, Nevada
(301) 529-5108
Allen.Gelfius@fda.hhs.gov