Traceability – Taking a Mock Recall to the Next Level

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Session Objectives

• Recognize the complexity of product tracing and the challenges it presents.
• Understand how traceability best practices can facilitate outbreak investigations
• Identify some key information/ criteria that you may want to incorporate in your business operations
• See the value of conducting mock traceback and mock recall exercises
What do we mean by Product Tracing?

The Supply Chain

Trace Back:
What is causing illness?

Trace Forward/Recall:
Where is the tainted food?
## Traceback vs. Recall

<table>
<thead>
<tr>
<th>Traceback</th>
<th>Recall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiated by regulators: balance making quick decisions with building a</td>
<td>Initiated by industry: protect public health and protect their firm and</td>
</tr>
<tr>
<td>regulatory case</td>
<td>bottom line</td>
</tr>
<tr>
<td><strong>Implicated product not known – reliance on epidemiology</strong></td>
<td><strong>Specific product(s) known</strong></td>
</tr>
<tr>
<td>Objective: identify points of convergence in supply chain to rule in/out</td>
<td>Objective: remove implicated product from the marketplace</td>
</tr>
<tr>
<td>suspect products</td>
<td></td>
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<tr>
<td>Relies on good recordkeeping by industry</td>
<td>Relies on good recordkeeping by industry</td>
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</tbody>
</table>
SESSION OVERVIEW

• This is an interactive tabletop exercise
• There are outbreaks going on in several states
• In each case, they seem to be associated with ice cream
• Are they related to each other?
• How does a firm respond to a public health emergency?
SESSION FORMAT

• Each table will pretend to be FDA and be alerted to related outbreaks in 2 states
• As a table, think about what questions you need to ask implicated firms
• A “company representative” will be at the podium to answer questions
• Move back in the supply chain and repeat the process until you figure out the source of the problem
The paperwork you will see may not have all the information on it that you include on your firm’s records!

This will involve group discussion and collaboration

Need to be able to deal with ambiguity!

Simulation of a possible scenario

Not all information is available at the outset; new information becomes available over time.

All materials will be collected at the end of the exercise

Time is short so focus on the **KEY QUESTIONS**; do not get distracted
KEY QUESTIONS

• Have you identified an implicated common ingredient for this outbreak?

• Have you identified a common source or point of supply chain convergence for this ingredient to get into both ice cream products?

• What would you suggest the industry voluntarily recall?
  • Date Range
  • Product Types

• What other activities, as a regulatory agency, would you be doing at this point?
  • Outside the scope: product/environmental testing results, recipients of products
Are there any questions?
GREEN STATE

• Baseball team eats frozen novelties from the Frosty Treats Ice Cream Truck on Saturday, May 6 after the game

• By Monday, May 8th, several teammates miss practice due to illness

• The week of May 15th, the local public health agency interviews the families. The majority of the ill team members and spectators indicated eating the “Choco Nutter Cone”. Those that ate other types of ice cream novelties were not sick.

• Almost two weeks later, the state public health lab identifies a rare strain, *Salmonella* sandilactis*, in the clinical specimens submitted from the majority of the ill individuals

• The isolates are uploaded to PulseNet at CDC on May 21

• The state investigators determine that Frosty Treats purchased the ice cream cone from Delivery Boss aka Food Boss

* Not a real Salmonella strain
YELLOW STATE

• On May 25, a second cluster of illnesses with the matching genetic fingerprint is uploaded from STATE YELLOW

• Interviews with the sick parties indicated that they all had also eaten ice cream, specifically, from half gallon containers of Chocolate Island Dream

• The ice cream had been purchased from Borrington’s Supermarket on May 10, 2012 and then eaten at a family reunion on May 11, 2012

• The identification on the ice cream carton is #IC24289811
Module 1 Questions

• What steps would you take next as the investigators from FDA?

• What questions would you ask of the Distributor (Food Boss) and Borrington’s supermarket?

• What are any possible food items that could have caused the illnesses in both clusters?
LET THE GAMES BEGIN!

• DON’T open the envelopes

• Please think about the questions that you need answered based on the outbreak information shared

• Let’s welcome the Borrington rep, followed by the Food Boss rep
COMPANY REPRESENTATIVES
IDENTIFIED POINTS OF SUPPLY CHAIN

Harper Ice Cream Manufacturer → Wholesaler 1 Food Boss formerly Delivery Boss → Frosty Treats Truck 1

Moonlight Valley Ice Cream Manufacturer → Borrington’s Retail 1
Module 2: UPDATE

• 3 days later you hold a conference call with the states to share information

• CDC reports two new clusters with a genetic match to the *Salmonella* sanidlactis in States Purple and Orange.

• The State A Gazette is reporting illnesses due to ice cream. The HHS Secretary’s office is calling you!
Module 2 Questions

• What steps would you take next as the investigators from FDA?

• What questions would you ask of the identified supply chain establishments?

• What are the production date ranges or product information that might be associated with this outbreak?

• Let’s welcome the Moonlight Rep, followed by Harper’s Rep
COMPANY REPRESENTATIVES
Module 3 Questions

• What steps would you take next?

• What questions would you ask of the identified supply chain establishments?

• How can you identify the possible implicated ingredients/product?

• What are the production date ranges or product information that might be associated with this outbreak?

Let’s welcome Smiley’s rep, followed by Broadway Best, and Limberton’s
BREAK –
10:00 am to 10:15 am
COMPANY REPRESENTATIVES
• 2 days later the federal agencies hold another conference call with the states to share information

• Purple state reports the Chocolate Island Dream ice cream in ½ gallon containers as the implicated product based on the epidemiologic investigation

• Orange state reports no association with ice cream and they are doing a case-control study on trail mix

• FDA reports on the laboratory sample analysis and confirms the isolation of *Salmonella* sandilactis from unopened choco nutter cones.

• CDC issues a web announcement about the outbreak
Next Steps…

- Have you identified an implicated common ingredient for this outbreak?
- Have you identified a common source or point of supply chain convergence for this ingredient to get into both ice cream products?
- What regulatory action or other activities would you take at this point?
- What would you suggest the industry voluntarily recall?
  - Date Range
  - Product Types
Traceback Wrap Up

- Which company’s paper work was the easiest to understand?
- Which companies paperwork gave the most trouble?
Traceback Best Practices

- IFT report to FDA made recommendations based on pilots using “real life” data and paperwork
- Does this exercise bring you to the same conclusions?
- What data are most useful for tracking products?
# CTEs and KDEs

<table>
<thead>
<tr>
<th>CTEs</th>
<th>Transportation (exchange of goods) - Shipping</th>
<th>Transportation (exchange of goods) - Receiving</th>
<th>Transformation (creation / manipulation of products) – Input</th>
<th>Transformation (creation/manipulation of products) – Output</th>
<th>Depletion (exit from system) – Consumption</th>
<th>Depletion (exit from system) – Disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Currently Required KDEs</strong></td>
<td></td>
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<tr>
<td>Event Owner (firm submitting information)</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
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<tr>
<td>Date/ Time</td>
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<td>R</td>
<td>R</td>
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<tr>
<td>Event Location</td>
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<td>R</td>
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<tr>
<td>Trading Partner</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td></td>
<td></td>
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<tr>
<td>Item (the good)</td>
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<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Lot/Batch/Serial#</td>
<td>BP*</td>
<td>BP*</td>
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<td>R</td>
<td>BP</td>
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<tr>
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<td>R</td>
<td>R</td>
<td>R</td>
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<td>R</td>
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<tr>
<td>Unit of Measure</td>
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<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
<td>R</td>
</tr>
</tbody>
</table>

**Linking KDEs**

<table>
<thead>
<tr>
<th>Activity Type (e.g., PO, BOL, Work Order)</th>
<th>C*</th>
<th>C*</th>
<th>R</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity ID (number associated with PO, BOL, Work Order)</td>
<td>C*</td>
<td>C*</td>
<td>R</td>
<td>R</td>
</tr>
<tr>
<td>Transfer Type</td>
<td>C</td>
<td>C</td>
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<tr>
<td>Transfer Number</td>
<td>C</td>
<td>C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lot/Batch Relevant Date</td>
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<td>C</td>
<td>C</td>
<td>BP</td>
</tr>
<tr>
<td>Carrier ID</td>
<td>C</td>
<td>C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trailer Number</td>
<td>C</td>
<td>C</td>
<td></td>
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</table>
Pilot Recommendation 6

- FDA should develop standardized, structured, and electronic mechanisms for industry to provide the Agency CTE and KDE product tracing data when requested during a specific food safety investigation.

- Paper is slow.
Pilot Recommendation 8

- If available, FDA should request CTE and KDE data for more than one up - one back in the supply chain
  - Totally optional (FSMA specifies FDA can’t require more than immediate recipient)
  - Having this information is the exception
Pilot Recommendation 9

- FDA should pursue the adoption of a technology platform to allow the Agency to efficiently aggregate and analyze data reported in response to a specific regulatory request.

- A “must have” if activity numbers are relied upon.
RECALL CONSIDERATIONS
Recall Considerations

• Pretend you are Broadway Best - now that you’re implicated, what do you do?

• What are all the things that need to be considered and coordinated?
REPORT OUT
How Did You Do? What Did We Miss?

- Activate recall team
- Define recall scope
  - How do you use paperwork to do that?
- Root cause analysis
  - What questions would you ask? What records are needed?
- Call lawyer and insurance company
- Draft communications
- Strategy to interact with regulatory agencies, interactions with customers etc.
- Identify spokesperson
Recall Plans

- FDA Preventive Controls rule proposed elements:
  - Written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions:
    - Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
    - Notify the public about any hazard presented by the food when appropriate to protect public health;
    - Conduct effectiveness checks to verify that the recall is carried out; and
    - Appropriately dispose of recalled food--e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.
What Recall Plan Do You Want?

(and “recall plan” sounds limiting)
What Else Should a Recall Plan Address? (and should it apply to other food crises)

<table>
<thead>
<tr>
<th>Corporate Quality Policy</th>
<th>Records Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership</td>
<td>Communications Capabilities</td>
</tr>
<tr>
<td>Organization</td>
<td>Systems Support</td>
</tr>
<tr>
<td>Roles &amp; Responsibilities</td>
<td>Review, Testing and Training</td>
</tr>
<tr>
<td>Incident Evaluation Process</td>
<td>Customer Knowledge</td>
</tr>
<tr>
<td>Additional Resources (internal and external)</td>
<td>Recall Strategy and Execution</td>
</tr>
</tbody>
</table>
Prepare a Toolkit in ADVANCE!

- Templates
- Press Releases
- FAQs
- Customer letters
- Shareholder letters
- Agency communications
- Checklists
- Recall Action Items
- Meeting Logs
- Contact Lists
  - Internal
  - External
Additional Resources

- Outside Counsel
  - Reviewed regulatory inspection policy
- PR firms
  - Reviewed communication templates
- Prepared for long term issues as well as short term
- Independent Voices
  - E.g., academics- interpret the science; put things in context
- Call centers
Recall Strategy Execution Should Include:

- Implementation of the Recall Strategy
- Swift and Effective Decision Making
- Efficient Utilization of Resources
- Clear Individual and Team Roles & Responsibilities
- Well Developed Systematic Approach
- Adequate Documentation
- Accurate and Timely Communications
Recall Communication Best Practice

• Best Practices:
  • Say what you know
  • Acknowledge what you don’t
  • Say what you’re doing to find out
  • Let them know when you’ll have more information to share
Closing Thoughts

Things to think about:

• Which paperwork is most like your company's?

• What can you do differently at your own company to help investigators?

• Are you prepared to be the target of this kind of investigation?

• Are you positioned to respond?
Resources

- Global Food Traceability Center [www.globalfoodtraceability.org](http://www.globalfoodtraceability.org)
- International Center of Excellence in Risk Communication [http://foodriskcommunications.org/](http://foodriskcommunications.org/)