Background and Development of Industry Collaboration Process

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Consultation with industry experts early in an outbreak investigation can provide important clues to help focus the investigation.

- Insights from industry can increase speed & ensure greater accuracy.


- Involved CDC, FDA, FSIS, industry, and consumer groups.
Consultation with Industry Representatives: Goal and Purpose

- To share information between the federal government and food industry early in a foodborne outbreak investigation, reducing the time needed to form an accurate picture of what is causing the outbreak and to implement control measures, like a food recall.

- Process is solely focused on leveraging current industry information to expedite the investigation and is not a means to inform industry as a whole about an outbreak.

- This process is distinct from industry interactions focused on collecting shopper card or distribution information from specific point(s) of service during the hypothesis generating/testing phase of the investigation.
Consultation with Industry Representatives: When is the Process Implemented

- Early in an investigation to assist with hypothesis generation about possible source(s) of contamination in a foodborne/enteric disease outbreak.
Consultation with Industry Representatives: Who Participates

- Participants will include federal government public health & regulatory officials and private sector representatives
  - Other potential subject matter experts, such as persons from industry associations or academia, who may provide expertise needed
  - State and local agencies are not included as part of this consultation, but this process does not replace existing coordination with state agency partners who may be involved in outbreak investigations.

- CDC working with FDA & FSIS determine appropriate consultants
  - Other federal agencies may be included depending on investigation

- If over the course of the investigation a potential conflict of interest is identified with any of the chosen consultants, they will no longer participate in consultations regarding that particular investigation
Consultation with Industry Representatives: The Convening Process

- CDC will be the primary agency that will convene a call
  - FSIS or FDA may at their discretion also choose to convene a call
- The moderator will not take formal notes, but a brief document/email with bulleted actions steps will be shared with participants and follow-up comments could be made via email
  - Documents should be brief, not require formal review from each participant (given the emphasis on speed)
  - Documents & other information should be treated as confidential
- One or more calls may be held over the course of an investigation.
  - Each call should be no more than one hour in length
- Once the relevant agency has determined that the investigation has reached a point where the regulatory process needs to be initiated, the consultation process will be closed and all communications will occur through the normal regulatory channels
Consultation with Industry Representatives: Types of Information Shared

- Types of information needed will be determined by the particular outbreak
  - Could include production practices, distribution patterns, consumer purchasing information, and other relevant information, such as food production, manufacturing, product testing, distribution, and supply chain information provided by private companies and trade associations.

- Information that is pre-decisional (trade secrets, financial, competitive harm, information or records used for litigation or law enforcement) and commercial, confidential information will not be shared.

- Consultants encouraged to share information they feel is relevant to the investigation, but should not share commercial/confidential information.

- Information discussed during the consultation should remain private and industry consultants should only share information with others for the purpose of making more information available to further the investigation.
  - The consultants should notify the federal agencies involved about any information they are sharing and with whom.
Consultation with Industry Representatives: Follow-up

- A debrief with industry representatives will be held to collectively learn from the experience in terms of both procedural and substantive issues
  - This call will ideally take place within a month of the final session of the consultation.
Examples Consultations with Industry Representatives during a Multistate Foodborne Disease Outbreak Investigation
Formal Industry Consultations

- **Mar 2013:** *Salmonella* Saintpaul (cluster 1303MLJN6-1)
  - Linked to imported cucumbers

- **Dec 2013:** Three clusters of listeriosis
  - No source identified

- **Sept 2014:** *Salmonella* Newport (cluster 1408MLJJP-1) and Javiana (cluster 1408MJGG-1)
  - Cucumbers from the DelMarVa peninsula

- **Aug 2015:** *Salmonella* Poona (cluster 1508MLJL6-1)
  - Linked to imported cucumbers
Two industry consultations calls: Mar 18 & 28, 2013
- Main focus of the calls were around the question of “do the data indicate any specific source at this point and what additional information would be helpful to move the investigation forward”

Trigger for calls
- Rapidly expanding outbreak of *Salmonella* Saintpaul infections with rare PFGE pattern
- Initial interviews of ~10 cases along with age, gender, and state distribution of the 26 reported cases suggested a fresh produce item, but not necessarily leafy greens
  - Many reported mangos, strawberries, or cucumbers

Outcome
- Consistent with fresh produce and possibly cucumbers from Mexico or SW United States
- Disturbance in the cucumber market due to major restaurant chain launching wrap containing cucumbers
Salmonella Saintpaul Cluster 1303MLJN6-1

- Call with general industry representatives: April 24
- Initial public announcement: April 25

[http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm349461.htm](http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm349461.htm)
Three Clusters of Listeriosis Possibly Linked to Deli Meat

- **Call held on December 17, 2013**
  - ~60 minutes in length
- **Trigger for call**
  - Based on combination of case interviews/epi information, testing of products from case patient homes, and laboratory data (including whole genome sequencing) some more unusual types of deli meat were suspected
PFGE Cluster Possibly Associated with Uncommon Deli Meats, 2012–2013

- 80% (12/15) reported eating deli meat
- Several reported uncommon deli meats (e.g., liverwurst, mortadella, ring bologna, cloth bologna)

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wgMLST analysis by Enteric Diseases Laboratory Branch, CDC
Salmonella Newport (cluster 1408MLJJP-1) and Salmonella Javiana (cluster 1408MJGG-1)

- **Call held on September 11, 2014**
- **Trigger for call**
  - ~200 cases of *Salmonella* Newport, mostly in mid-Atlantic states or among travelers to the Delmarva Peninsula
  - PFGE pattern previously linked to outbreaks with tomatoes harvested from the Delmarva Peninsula of Virginia in 2002, 2005, 2006, and 2007
  - Initial interviews indicated a possible link to a fresh produce item (tomatoes, cucumbers or lettuce)
  - ~70 cases of *Salmonella* Javiana with same epidemiologic features as the Salmonella Newport cases.

- **Outcome**
  - Consistent with fresh produce item from Delmarva
  - Restaurant clusters will provide useful information on tracebacks
Outbreak of *Salmonella* Newport Infections Linked to Cucumbers – United States, 2014

*Weekly*

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In August 2014, PulseNet, the national molecular subtyping network for foodborne disease surveillance, detected a multistate cluster of *Salmonella enterica* serotype Newport infections with an indistinguishable pulse-field gel electrophoresis (PFGE) pattern (XbaI PFGE pattern JIPX01.0061).* Outbreaks of illnesses associated with this PFGE pattern have previously been linked to consumption of tomatoes harvested from Virginia's Eastern Shore in the Delmarva region and have not been linked to cucumbers or other produce items (1). To identify the contaminated food and find the source of the contamination, CDC, state and local health and agriculture departments and laboratories, and the Food and Drug Administration (FDA) conducted epidemiologic, traceback, and laboratory investigations. A total of 275 patients in 29 states and the District of Columbia were identified, with illness onsets occurring during May 20–September 30, 2014. Whole genome sequencing (WGS), a highly discriminating subtyping method, was used to further characterize PFGE pattern JIPX01.0061 isolates. Epidemiologic, microbiologic, and product traceback evidence suggests that cucumbers were a source of *Salmonella* Newport infections in this outbreak. The epidemiologic link to a novel outbreak vehicle suggests an environmental reservoir for *Salmonella* in the Delmarva region that should be identified and mitigated to prevent future outbreaks.
Salmonella Poona (cluster 1508MLJL6-1)

- Call held on August 26, 2015

- Trigger for call
  - >100 cases reported in a one week period
  - 20 States (mostly out West) have reported cases, median age is 11 years, and 55% are female.
  - Based on preliminary interviews, this appears to be an FDA regulated product (possibly cucumbers, melons, leafy greens, or a perhaps a fruit)

- Outcome
  - Cucumbers or melons could be a reasonable vehicle
    - Age distribution seemed a bit young for cucumbers
    - Less likely to be tomatoes based on distribution
    - Consistent with a product grown in Mexico or South Western US
Multistate Outbreak of *Salmonella* Poona Infections Linked to Imported Cucumbers

Posted October 14, 2015 3:00 PM ET

**What's New?**

- Since the last update on October 6, 2015, 35 more ill people have been reported from 14 states. Given the delay between when someone gets sick and when that illness is reported to public health, it is not unexpected to continue to see illnesses reported after the recalls.
- Florida was added to the list of states with ill people, bringing the total number of states to 36.

**At A Glance**

- Case Count: 767
- States: 36
- Deaths: 4
- Hospitalizations: 157
- Recall: Yes

**Highlights**

- Read the Recall & Advice to Consumers, Restaurants, and Retailers >>
- CDC, multiple states, and the U.S. Food and Drug Administration (FDA) are investigating a multistate outbreak of *Salmonella* Poona infections. This investigation is ongoing. CDC will provide updates when more information is available.
- Epidemiologic, laboratory, and traceback investigations have identified cucumbers imported from Mexico and distributed by Andrew & Williamson Fresh Produce as a likely source of the infections in this outbreak.
- 767 people infected with the outbreak strains of *Salmonella* Poona have been reported from 36 states, an increase of 35 cases since the last update on October 6.
  - 157 ill people have been hospitalized, and four deaths have been reported from Arizona (1), California (1), Oklahoma (1), and Texas (1).
Summary - Industry Consultation Process

- Process in place and used several times
- Consultation with industry experts early in an outbreak investigation can provide important clues to help focus the investigation on the foods or food ingredients
  - Insights from industry can increase the speed and ensure greater accuracy of the investigation
- This process is a useful addition to other industry interactions early in outbreak investigations focused on collecting shopper card or distribution information from specific point(s) of service
Thank you

The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the Centers for Disease Control and Prevention.