



# Retrospective Outbreak Investigations Initiated by Product or Environmental Sampling

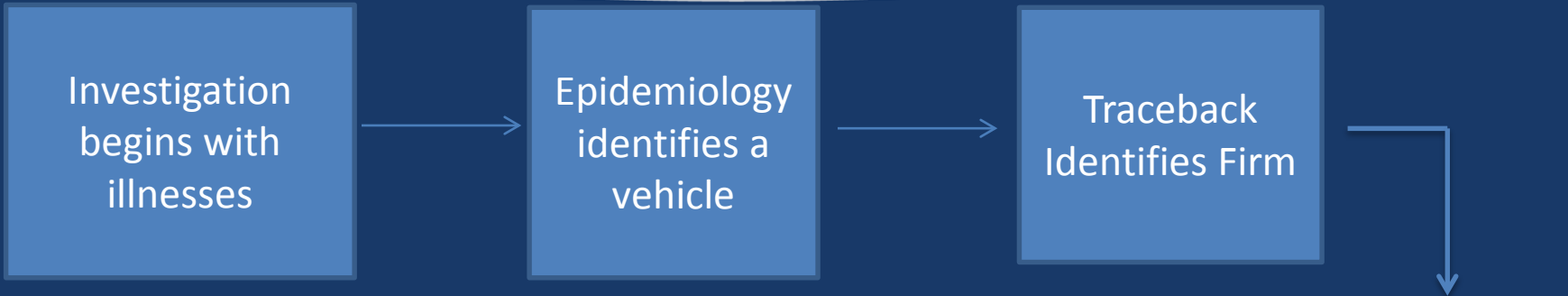
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# Traditional VS Retrospective Outbreak Investigations

Traditional



Retrospective



# ROIs and CORE

CORE Mission	CORE Phase	Traditional outbreak investigations	Retrospective Outbreak Investigations (ROIs)
Find the outbreak	Signals	Illness cluster identified first; epi/traceback/lab ID vehicle and responsible firm	Positive product/envir. sample obtained; cases determined by molecular subtyping and epi (exposure info)
Stop the outbreak	Response	FDA Response including Recall, Enforcement Actions and Communications to remove contaminated product from commerce and alert the public	
Prevent the Next Outbreak	Post Response	Evaluation of lessons learned from the investigation to develop and implement strategies to prevent future outbreaks and evaluate key findings to effect policy change	

# Why Focus on this Now?

- Determining if positive samples relate to human illnesses is not new
- PFGE match not always enough evidence to investigate further, especially for *Salmonella* spp
  - ★ Pattern commonality concerns, resource constraints
- Whole genome sequencing (WGS) provides greater resolution to target potential clusters

# The Changing Face of Outbreak Detection and Response

- Currently transitioning from the PFGE era to the Whole Genome Sequencing (WGS) era
- Use of WGS to identify clusters (as opposed to PFGE) will result in:
  - ★ Identification of more clusters but smaller case counts
  - ★ Shift in understanding of what is an outbreak by expanding temporal boundaries, challenging current understanding of “ongoing”

# Examples of Past ROIs

- *Salmonella* Braenderup in nut butters (2014)
- *Listeria monocytogenes* in ice cream (2015)

# *Salmonella* Braenderup in nut butters (2014)

- Environmental samples collected by FDA as part of an inspectional assignment at nSpired Natural Foods
- Cases matching rare PFGE and WGS investigated by CDC/states
  - ★ 4/5 cases virtually identical by WGS; 3/4 confirmed to have eaten an nSpired product
- Products recalled, firm voluntary closure, corrective actions initiated

# *Listeria monocytogenes* in Ice Cream (2015)

- Product samples collected by South Carolina
- Initial follow-up coordinated via Center for Food Safety and Nutrition (CFSAN)
  - ★ Transition to CORE Response when 4 KS cases identified with matching rare PFGE patterns and exposure history
- Products recalled, firm shut down, corrective actions initiated
- Identification of novel food/pathogen pair



# Why Does this Matter?

- Retrospective Outbreak Investigations support FDA's implementation of a prevention-centric focus under FSMA
  - ★ Smaller clusters, fewer cases
  - ★ Improved targeting of state and federal resources
  - ★ Enhanced attribution and novel pathogen/commodity pairs identified

# Smaller clusters, Fewer Cases: PB History

## Traditional Outbreak Investigations

- *Salmonella* Tennessee (Con Agra/Peter Pan PB, 2006/2007):  
715 cases, 129 hospitalizations, no deaths
  - *Salmonella* Typhimurium (peanut products/PCA, 2008/2009):  
714 cases, 166 hospitalizations, 9 deaths
  - *Salmonella* Bredeney (Sunland/Trader Joe's PB, 2012):  
42 cases, 10 hospitalizations, 0 deaths
- 
- *Salmonella* Braenderup (nSpire/nut butters, 2014):  
6 cases, 1 hospitalization, no deaths

Retrospective Outbreak  
Investigation

# Smaller clusters, Fewer Cases: Ice Cream

How many cases were prevented??

# Improved Targeting of State and Federal Resources

- Greater confidence in relationship between human illness and responsible firm
  - ★ Always have laboratory confirmation of the vehicle because ROIs begin with a product or firm
- Avoids some limitations of traditional outbreak investigations
  - ★ Food Exposure collinearity
  - ★ Tracebacks that do not converge (e.g. due to poor food exposure histories)

# Enhanced Attribution, Identification of Novel Pathogen/Food pairs

- Ability to attribute “baseline” cases
  - ★ Cases that previously would not have triggered traditional cluster detection methods
- Identification of Novel Pathogen/Food pairs
  - ★ Provides a more refined approach to understanding which foods cause illnesses
  - ★ Increases our understanding of pathogenic microorganisms
  - ★ Leads to novel prevention strategies

# Where do we go from here?

- Roles and Responsibilities
  - ★ FDA | CDC | States
- Parameters/scope of investigations
  - ★ Identifying which potential food/illness groups to investigate for epidemiologic information
  - ★ Involves consideration of parameters such as temporal boundaries, molecular subtyping and scalability
- How does this integrate with other major initiatives (FSMA)

# Challenges

- Data Interpretation
- Resources
  - Sampling- product and environmental
  - Outbreak investigation and prioritization
- Strength of Evidence

# Questions?