FDA’s Environmental Assessment Approach

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Outline

• What is an EA?
• Who, What, When, Where, Why
• FDA’s approach to institutionalizing EAs
• Recent EAs
What is an environmental assessment?

- An in-depth, multi-disciplinary, systems-based approach to determining how contamination may have occurred, and proliferated so it can be prevented in the future.

- How did the “environment” contribute to the introduction, transmission and proliferation of pathogens or other hazards that caused illness or contamination?
Purpose of an EA

- Identify potential contributing factors, environmental antecedents, and control strategies

Short term goal:
- Provide the basis for corrective actions to prevent potential future contamination events at the site(s)

Long term goals:
- Inform the Agency’s regulatory policies and decisions
- Identify trends in probable causes and potential preventive controls that may be more broadly applicable to the industry
Examples of contributing factors and environmental antecedents

At a processing facility:
- Contributing factor might be contaminated water
- Root cause might be a failing sewage system that is contaminating the water
- Control strategy could involve redesigning the sewage system and implementing a maintenance schedule.

At a farm:
- Contributing factor might be drainage from a RV park adjacent to the irrigation canal
- Root cause might be that the soil at the RV park is not suitable for septic absorption, thus leading to overflow into the canal
- Control strategy could be to install physical barriers to prevent draining
When is an EA conducted by FDA?

Not conducted for every foodborne illness outbreak or contamination event

- Factors considered:
  - Whether a new hazard or pathogen/food combination is causing illness;
  - Whether the assessment has the potential to identify new probable causes or preventive controls;
  - Inspectional history and observations associated with the firm;
  - Severity of public health outcomes associated with the incident;
  - Timing – how much time has passed since the contamination
Where?

- Environmental assessments are NOT only conducted on farms
- Can be conducted at
  - Farms
  - Packinghouses
  - Facilities that manufacture/process, pack, or hold food
What is assessed?

The definition of “environment” will depend on where the investigation is carried out

**Farm**
- Water
- Soil amendments
- Harvesting
- Animal intrusion
- Adjacent Land use
- Employee health & hygiene
- Packinghouse/equipment
- Cleaning and sanitation...

**Manufacturing facility**
- Water
- Processing & handling
- Sanitation practices
- Supplier controls
- Storage controls
- Employee health & hygiene
- Transportation
- Testing
Who?

Multi-disciplinary team that could involve local, state, and federal government agencies

- Team led by a trained regulatory investigator
- Subject Matter Experts (SMEs)
  - Environmental Health Specialist
  - Microbiologist
  - Water quality expert
  - Sanitation expert
  - Food technologist
  - Veterinarians and/or commodity specialists
Why now?

Long term goal:

Prevent outbreaks and contamination events before they occur

• More interest in “root cause analysis”
• FSMA – focus on prevention
FDA’s Approach to Institutionalizing EAs
FDA’s EA Procedures Document  
*(In draft)*

- Provides direction in conducting EA activities
- Assists FDA staff in documenting activities associated with an EA
- Where it will be published?
  - **Short Term**
    - Add a citation/web link in the IOM referencing the Procedures Document
  - **Long Term**
    - Add the Procedures Document as a section of the IOM
Allow for collaboration within FDA and with partner agencies

- Steering Committee goals:
  - Institutionalize EA activities throughout FDA
  - Ensure that procedures are complementary to efforts by RRTs
  - Develop roll-out plan encompassing all EA activities
  - Advise EA Workgroups
    - IOM Workgroup
    - Data Workgroup
    - Training Workgroup
Data Workgroup

• Goals:
  ★ Determine data elements to capture
  ★ Evaluate current farm questionnaire; update if applicable
  ★ Develop EA data collection form for manufactured foods
  ★ Determine data housing, maintenance, and analysis

• Current status
  ★ Determining farm EA data elements
  ★ Revising FDA’s Farm Questionnaire
Training Workgroup

• **Goals:**
  - Develop training strategy and implementation plan
  - Use Job Task Analysis to determine appropriate training needs
  - Develop materials for training

• **Proposed timeline:**
  - February: Job Task Analysis by focus group
  - March: Validation of JTA
  - March-June: Develop materials
  - July: Pilot
Working together to harmonize EA efforts

CDC
Environmental Health Services Branch

FDA
District Offices, HQ, SMEs

RRTs
EA Workgroup
What is being done in the meantime?

**EAs continue to be conducted**

- Recent Multi-state Outbreak of Cyclosporiasis
  - Procedures document used as a guide for EA team
  - Multi-disciplinary team from FDA, CDC, and Mexico
  - Data collected using current farm questionnaire
  - EA report expected to be published on FDA.gov on Thursday, November 21
Other EAs conducted

• *E. coli* O145 associated with romaine lettuce (2010)
• *Listeria monocytogenes* associated with cantaloupes (Jensen Farms, 2011)
• *Salmonella* associated with cantaloupes (Chamberlain Farms, 2012)

http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm235425.htm
EA conducted at Chamberlain Farms
*Salmonella* Typhimurium/Newport in cantaloupe

- Regulatory inspection identified:
  - multiple deficiencies, esp. in the packinghouse
  - Packinghouse and field cantaloupe positive for outbreak strains

- **Collaborative EA by IN Department of Health and FDA**

- All aspects of firm’s environment were evaluated
  - Growing environment
  - Agricultural water
  - Packing/Holding operations and practices
  - Adjacent land use/regional practices
EA conducted at Chamberlain Farms
Salmonella Typhimurium/Newport in cantaloupe

• Outbreak strain detected in soil
• Non-outbreak strains of *Salmonella* detected in soil, non-commercial field cantaloupe, and man-made field ditch
• Agricultural water sources were negative for *Salmonella*
• Possible sources of contamination hypothesized by team and recommendations addressed in report

- *Biological soil amendments may have been the source of the pathogen. However, the firm reported no use of them.*
- *Significant poultry (turkey) production is located in the local region, but the firm stated it did not use poultry manure.*
- *Agricultural water may have been a vehicle for the spread of contamination*
Outbreak & EA Findings - Cantaloupes

• Example of what findings can be used for:

  **2013 Cantaloupe Packinghouse Assignment**

• Inspections with sampling component

• Aim is to assess current practices and identify insanitary conditions that may affect the safety of cantaloupe

• If adverse findings found, FDA will take action as needed

• Letter to cantaloupe industry:

  [Link](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAEelectronicReadingRoom/ucm341029.htm)
Website

FDA Environmental Assessment website:

http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm235425.htm