



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)

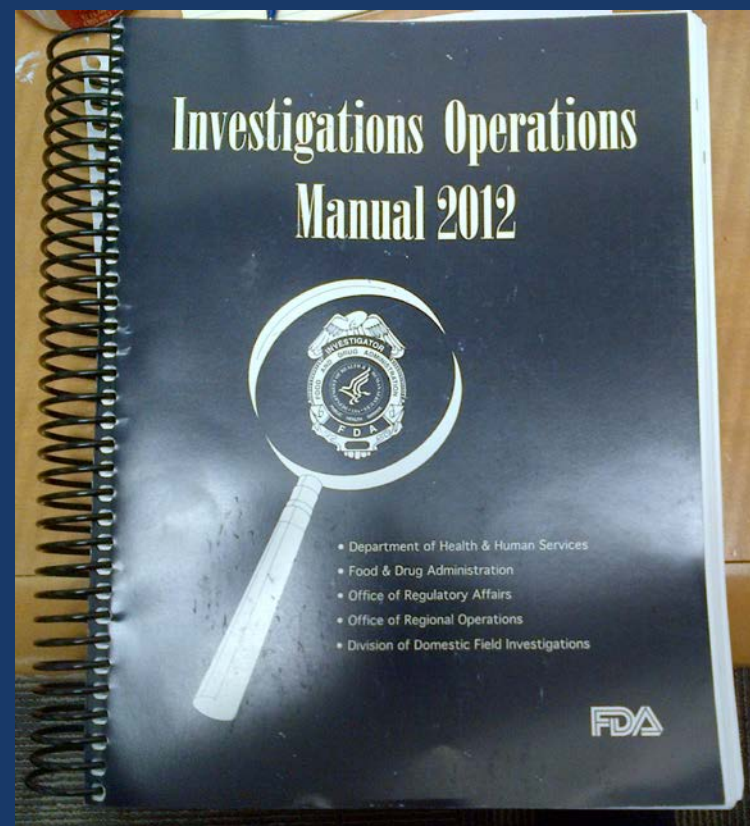
- Provides direction in conducting EA activities
- Assists FDA staff in documenting activities associated with an EA
- Where it will be published?

★ 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



Workgroups

Allows 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

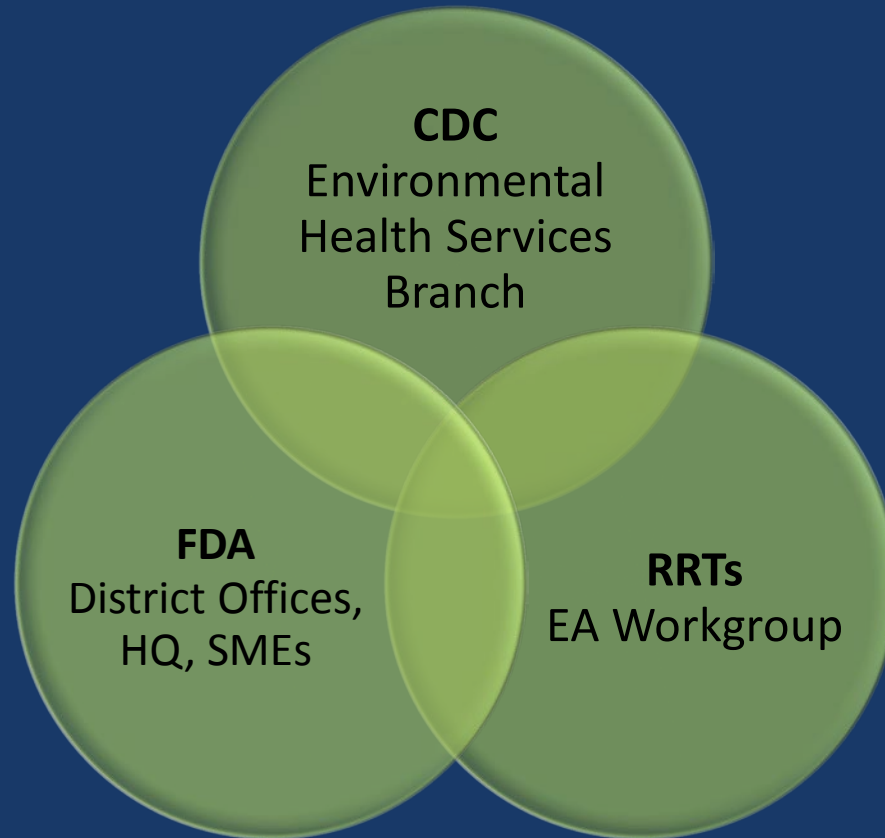
Data Workgroup

- 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



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:

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/ucm341029.htm>

Website

FDA Environmental Assessment website:

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

The screenshot shows a Windows Internet Explorer browser window displaying the FDA website. The address bar shows the URL: <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm235425.htm>. The browser's address bar also shows a search for "FDA cantaloupe assignment".

The website header features the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". A search bar is visible on the right side of the header. Below the header is a navigation menu with the following items: Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products.

The main content area is titled "Food" and includes a breadcrumb trail: Home > Food > Recalls, Outbreaks & Emergencies > Outbreaks. A sidebar on the left contains a list of links: Recalls, Outbreaks & Emergencies, Outbreaks, Outbreak Investigations, Environmental Assessments (highlighted), About the CORE Network, and Resources & Related Links.

The main content area displays the title "Environmental Assessments" and the subtitle "Triggered by Foodborne Illness". Below this, there is a list of links: Introduction, The Role of Environmental Assessments in Foodborne Illness Outbreak and Prevention, and Assessments. The "Assessments" link is selected, leading to a page titled "Factors Potentially Contributing to the Contamination of Fresh Whole Cantaloupe Implicated in a Multi-State Outbreak of Salmonellosis February 2013". The text on this page reads: "This assessment provides an overview of FDA's findings and observations of factors that potentially contributed to the contamination of fresh, whole cantaloupe with the pathogen *Salmonella* Typhimurium and/or *Salmonella* Newport, which was implicated in a 2012 multi-state outbreak of salmonellosis." Below this text is a link to "FDA Overview of FSMA's Proposed Produce Safety Rule and Chamberlain Farms Environmental Assessment (PDF, 6MB)".

The browser's taskbar at the bottom shows the Windows Start button, several application icons, and the system tray with the date and time: 12:00 PM 11/19/2013.