Use of Root Cause Analysis by Government Regulatory Programs

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Root Cause Analysis

- What went wrong, how, and WHY
- Rarely a single cause
- Resource intensive investigation
- Depends on cooperation from multiple agencies and industry

FDA Environmental Assessment (EA)

- The purpose of an EA is to identify *contributing factors* and *environmental antecedents* that led to the contamination or food safety event, and to provide recommendations to prevent reoccurrence, otherwise known as “root cause analysis.”

Factors Considered for Proposing an EA

- Laboratory data/evidence
- Traceback data
- Epidemiological data
- Historical outbreak data related to the suspected commodity and pathogen
- Historical research on the area(s) affected
- Timing of outbreak and contamination
- Scope of the EA suggested
- Recurrence
- Funding
- Inspectional history of firm/farm/commodity implicated

Five “Whys”

- EAs involve asking “Why?” repeatedly.
  - Why did people get sick? Because the food was contaminated.
  - Why was the food contaminated? Because the processing line was contaminated.
  - Why was the processing line contaminated? Because *Listeria monocytogenes* was present in brushes used to clean the line.
  - Why was *Listeria monocytogenes* in the brushes? Because the brushes were used to clean the floor before being used on the equipment.
  - Why …?

Execution of an EA

- Collaboration with the firm
- Worksheets/Questionnaires
- Critical thinking – hypotheses may change
- Sample collection/types of samples
- Documentation/Photographs

FDA “Environmental Assessments”

- “Environmental Assessments” webpage
  - https://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm235425.htm
- Four Assessments posted
  - *Cyclospora* illnesses linked to salad mix
  - Salmonella linked to cantaloupes
  - Listeria linked to cantaloupes
  - *E. coli* illnesses linked to Romaine lettuce

EAs May not Uncover the Root Cause

- It may be impossible to reconstruct what happened when the contamination event occurred – conditions and behaviors may have changed.
- Time and resource constraints may prevent an EA from being able to determine a root cause.
- It may be possible to identify contributing factors but not the true root causes.

“Negative EAs” Still Provide Useful Information

- Recommendation for research to determine if *Cyclospora* is reasonably likely to be a food safety hazard associated with the specific leafy green growing region
- Recommendation that the firm establish procedures for the hand wash facilities to facilitate the control, reduction, and elimination of human pathogens from employee hands

How Does FDA Use Environmental Assessments?

- Communicates information to the industry and the public through EA reports.
- To inform the development of guidance targeted to preventive controls and produce safety rules.
- To inform regulatory actions as appropriate.
- To direct FDA resources to areas identified as contributing to problems, e.g., during inspections.

Key Points

- FDA uses environmental assessments (EAs) to conduct root cause analyses.
- EAs are VERY resource intensive, so we must be judicious in their use.
- EAs require a cooperative approach among government agencies and industry to be effective.
- The results of EAs need to be disseminated so industry can use the information to enhance food safety practices to prevent recurrence.

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