Collaborative Food Safety Forum (CFSF)

Root-cause Analysis: Workshop Key Themes

October 17 & 18, 2016
Washington, D.C.

1. Meeting goals & objectives:

Goal:
Improve food safety by incorporating lessons learned from root-cause analyses conducted in the context of foodborne illness outbreaks and "near misses," as well as from root-cause analyses conducted in other sectors.

Objectives:
- Develop a common understanding around root-cause analysis, including:
  - Definition and core components
  - Value and expectations for improving food safety
- Identify potential areas for improving root-cause analysis
  - What makes a successful root-cause analysis?
  - What are common challenges and how they can be overcome?
- Extract more value from future root-cause analyses
  - Examine approaches to overcoming common challenges to sharing lessons learned from root-cause analysis
  - Propose additional next steps/actions

2. Working definition of root-cause analysis (based on USDA-APHIS definition with modifications)

"Scientifically rigorous and methodological investigation analysis used to identify the 'who, what, where, when, why, and how' of a food safety problem that occurred. The goal is to determine underlying reason(s) that caused a problem and what actions can be taken to address the problem."

Reasons for developing a working definition:
- Varying definitions of root-cause analysis (e.g., regulatory agency vs. industry, food industry vs. other industries, foodborne outbreak vs. 'near misses') undermine ability to sharing lessons learned.
- Varying expectations around root-cause analysis:
  - Scientific rigor -> confidence in the analysis and findings
  - Actionable results – ability to turn results into concrete actions
  - Depth of analysis (i.e., when has analysis uncovered the true root causes)
  - Value proposition (why expend the resources)
  - Optimal resource allocation (not every event may merit root cause)

3. Value of root-cause analysis
- Understand what went wrong, why, and what actually worked
- Prevent food safety problems from recurring

- Identify areas for improvement (including process vulnerabilities that *could have* caused a food safety problem)
- Through continuous process improvement, move towards a prevention-based system
- Improve food safety culture (e.g., across food chains, between regulators and industry) through collaboration, transparency and data sharing
- Build trust with consumers, customers and other stakeholders through rigorous analysis, continuous process improvement, and clear communication
- Target and deploy resources (e.g., funds, staff time) strategically and in most effective way
- Identify best practices that can move a whole industry forward and inform regulations or guidance

4. Characteristics of good root-cause analysis
   - *Comprehensive* – identify and prioritize all process vulnerabilities, including those that did not contribute to the particular food safety problem but could in the future
   - *Systematic* – based on a methodological, systematic approach that assures rigorous analysis
   - *Timely* – evaluates conditions at the time problem occurred, not at time of investigation
   - *Flexible in scope* – appropriate to the analysis
   - *Scalable* – many industry stakeholders are performing root-cause analysis on a routine basis to investigate process abnormalities; significantly different scope than analysis of major outbreaks
   - *Relevant* – identifies system vulnerabilities that can be addressed and were not recognized previously
   - *Evidence-based* – findings and conclusions are based on scientific evidence rather than conjecture
   - *Multi-disciplinary* – requires experts from different backgrounds (e.g., food technologists, microbiologists, behavioral psychologists, engineers)
   - *Collaborative* –collaboration across sectors (e.g., government, academia and industry, within and across industry segments, etc.) enhances the value of an analysis
   - *Actionable* – identify concrete vulnerabilities and tangible approaches to address them
   - *Separate and apart* from issue response – focus is not to react to the food safety problem at hand and just identify the food vehicle, rather, to identify how the vehicle became contaminated in order to prevent the problem from reoccurring in the future (competing priorities for key staff can be a challenge)

5. Resource needs to conduct root-cause analysis:
   - Clear operational structures
   - Trained (and experienced) staff with adequate time to conduct a thorough analysis
   - Adequate resources (e.g., to conduct laboratory analyses and other required tests)
   - Effective data collection and management systems
   - Rigorous analytics
   - Data and information-sharing

6. Challenges associated with root-cause analysis
   - Unclear mandate
   - Lack of leadership commitment
   - Resource limitations
   - Need for specialized training and expertise
     - What to do and how to do it
     - What to focus on and when to appropriately narrow scope

    - What are the actual root causes (as opposed to contributing factors or symptoms of root causes)
- Inability to conduct broad scrutiny (i.e., can investigate beyond initial hypothesis, no need to narrow investigation too quickly)
- Exposure to liability hindering data and other information sharing
- Concern about brand protection / protection of confidential business information
- Timing (competing requirements for resources and staff time during a crisis) and general demand on time of staff
- Need for prioritization
    - Not all root-cause analyses provide equal amount of value
        - Differentiate outbreaks/near misses due to known causes versus those due to 'novel' causes and prioritize them as appropriate
- Need platforms to share results
    - Between regulators and industry
    - Between large and small operations
    - Across industry segments

7. <u>Opportunities for improvement</u>
    - Research quantifying the value of root-cause analysis
        - Business case
        - Public health case
        - Improvements in industry standards / best practices
    - Alignment around definition, methodology and best practices for root-cause analysis
        - Consensus building
        - Identification of further research needs
    - Litigation and liability-related issues *(issues were raised but require more scoping and expert, legal input)*
    - Research needs to improve root-cause analysis
        - Identify root-cause analysis trends and best practices
        - Evaluate existing root-cause analysis competencies and competency gaps
        - Evaluate behavioral change models to implement root-cause analysis findings
    - Improve data collection and information sharing
        - Platforms
        - Incentives
        - Analysis of data on 'near misses'
    - Ability to learn from best practices in other disciplines
        - Conducting root-cause analysis
        - Sharing lessons learned
    - Provide resources (capacity and competency) to conduct root cause analysis to smaller operators with severe resource constraints

8. <u>Immediate next steps: Pilot project to share root-cause analysis lessons learned for *Listeria*</u>
    - *Objective:* bring together experts from different industry segments and settings (industry, academia, government) to share root-cause analysis experiences and lessons learned
    - *Goals:*
        - Demonstrate value of root-cause analysis
        - Determine value of sharing information and lessons learned
            - Identify effective mechanisms for information sharing
        - Identify best practices for
            - Conducting root-cause analysis

        - Sharing information and lessons learned
- *Scope:*
    - Face-to-face meeting, possibly paired with written proceedings to share information more broadly
    - Include experts from different industry segments, academia and government (federal, state, and local)