

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Enhancing Root Cause Analysis Examples, Challenges, and Lessons Learned

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- Defining Root Cause
- Illustrate examples using FSIS investigations
 - When is a root cause assessment needed?
 - Challenges that limit identification of root cause
- Lessons learned and recommendations

Root Cause Assessment to Prevent Illness

- Ultimate goal is to identify a permanent solution to a food safety hazard and establish logical problem solving processes for future application
- Assessments provide insight into risk factors that contribute to contaminated food and human illness
- Identifying root cause(s) is a process that we practice and develop to refine methods for problem-solving
- Supports policy development and modernization efforts targeted at addressing food safety vulnerabilities

Root Cause Assessment: From Farm to Consumer



Risk Factors to Consider from Farm to Consumer

On Farm

- Animal husbandry
- Contaminated feed
- Wildlife/environmental exposures
- Herd/flock additions





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Transport

- Contaminated trucks
- Sale barn exposures
- Mixing of animals
- Stress
- Lowered livestock immunity

Retail & Consumers

- Temperature abuse
- Cross-contamination
- Undercooking
- High-risk populations 6

Slaughter/Processing

- Contamination/transmission during lairage
- Sanitary dressing issues
- Storage and transport

Questions that FSIS Routinely Address

- Does establishment have a Sanitation SOP and HACCP Plan to prevent and control hazards?
- Where in the process have critical control points (CCPs) been identified? What interventions are used at these points? Are they scientifically valid?
- Are CCPs monitored at the proper frequency, as directed in HACCP plan? What corrective actions taken in response to CCP deviations? Is recordkeeping adequate to demonstrate the food safety system is working as designed?

Food Safety and Inspection Service: FSIS Investigation at Slaughter

- Are animals handled humanely with minimal stress?
- Is carcass handled in a sanitary manner to prevent contamination (e.g. free of fecal material or ingesta)?
- Is carcass temperature properly controlled to minimize outgrowth of bacteria that are present?
- How is compliance monitored to ensure food contact surfaces are regularly cleaned?





FSIS Investigation at Processing

- Does the establishment take measures to prevent and control hazards on incoming ingredients?
- When raw or not-ready-to-eat (NRTE) product is labeled with cooking instructions, have these been validated?
- For RTE products, is the lethality step sufficient to eliminate or adequately reduce pathogens?
- Do cooked products meet cooling guidance criteria to prevent bacterial outgrowth?
- After lethality steps, are measures taken to prevent contamination of cooked products?

2015 Salmonella I 4, [5], 12: i:- Investigation

- 192 case-patients from 5 states (AK, CA, ID, OR, WA); 188 infected with Salmonella I 4,[5],12:i:-
 - Illness onset: 4/25/15 9/25/15
 - 17% (30/180) hospitalized
 - 76% (94/123) consumed pork
- Resistance: ASSu in 1 and ASSuT in 20 clinical isolates
- FSIS traceback identified Establishment A (Est. A) as source of pork or whole hogs for case-patients attending pig roasts
 - Notice of intended enforcement issuance
 - FSIS recall: 116,262 pounds of whole hogs

Food Safety and Inspection Service: Intensified Sampling

- Intensified sampling at Est. A during the outbreak:
 - Salmonella I 4,[5],12:i:- isolated from all cecal samples, several carcass swabs and pre-operational environmental swabs
 - 93% (14/15) isolates had ASSuT AMR profile
 - All *Salmonella* I 4,[5],12:i:- isolates indistinguishable from the main outbreak PFGE pattern
 - Sampling results revealed insanitary conditions at Est. A, leading to a recall expansion of 523,380 pounds of pork products

Collaboration to Explore Root Cause

- Based on traceback findings to farms in Washington and Montana, Washington State's Department of Health expressed interest in investigating suppliers
- In 2014, APHIS and FSIS signed MOU to clarify procedures and responsibilities in assessing on-farm root cause factors in foodborne outbreaks
- FSIS consulted with APHIS Veterinary Services to determine if activation of the FSIS/APHIS memorandum of understanding would facilitate progress in identifying cause of contamination

Food Safety and Inspection Service: Root Cause Considerations

- Abundance of evidence implicated slaughter establishment as source of contamination, hence interventions focused there
- APHIS gathered data from suppliers for Est. A as well as other federal establishments not associated with contamination
- APHIS agreed to continue collaboration with FSIS and industry to enhance understanding of pre-slaughter risk factors
- Operational framework for pre-harvest investigations being developed by APHIS in partnership with industry
 - Develop procedures and processes for when on-farm or other pre-harvest investigations might be warranted

Efforts Towards Roaster Pig Food Safety



Research Root Cause Efforts

- 2016 National Pork Board call for research focuses on:
 - Identifying characteristics that potentially make 4,5,12,i.serotype unique
 - Swine health concerns
 - Environmental adaptability of organism
 - Heat tolerance of organism
 - Effectiveness of pre-harvest and processing measures to eliminate infection
- FSIS, with assistance from State partners, has shared isolates to support research efforts, which are underway
- FSIS and NPB planning study with academic researchers on thermal image mapping for cooking roaster pigs

2016 Salmonella I 4, [5], 12: i:- Investigation

- 63 case-patients from 13 states (West Coast focus)
 - Illness onset: 7/5/16 1/24/17
 - 27% hospitalized
 - 88% case-patients report consuming chicken, including 60% case-patients who reported consuming rotisserie chicken products from 11 chain B locations
 - Whole genome sequencing data identified ASSuT or tetracycline resistance
- On 10/9/16, FSIS issued a public health alert for rotisserie chicken salad produced from 8/26/16 to 9/2/16 at a WA chain B location

Efforts Towards Rotisserie Chicken Food Safety

- FSIS visited 4 chain B stores, noting potential for undercooking & cross-contamination
- Chain B retrained employees on rotisserie chicken process
- Adjust cooler temperatures to minimize ice on chicken so starting temperatures for cooking are more consistent
- Worked with suppliers to standardize chicken size
- Explore use of wireless thermometer system
- FSIS will submit best practices to Conference for Food Protection (CFP) to avoid undercooking and crosscontamination during rotisserie chicken preparation

Using FSIS Research Priorities to Address Root Cause



Food Safety and Inspection Service: **Research Priorities in Action**

- Multiple outbreaks linked to poultry during 2011-2013
 - Salmonella Hadar, ground turkey
 - Salmonella Heidelberg, ground turkey
 - Salmonella Heidelberg, chicken
- Questions raised about characteristics of outbreak strains that potentially increase virulence potential
- FSIS promoted topic as a research priority for the agency

Food Safety and Inspection Service: Lessons Learned

- Multiple factors contribute to determining the root cause(s) of an outbreak in a timely manner
- Detailed findings involve multiple levels:
 - Practices (on-farm, transport, slaughter, processing)
 - Traceback (records, receipts, shopper cards)
 - Lab data (Whole genome sequencing)
 - Findings at retail
 - Consumer handling practices

By identifying the factors contributing to contaminated food, root cause assessments can help to stop outbreaks and prevent future ones



Next Steps and Recommendations

- Continue work with APHIS, CDC, State and local partners as well as industry to identify opportunities for pre-harvest investigation if data justifies further work
- Engage key stakeholders and use guidance with decision trees to consider options as early as possible during an outbreak investigation
- Shift focus from "on-farm" to identifying critical control points along entire farm-to-fork pathway

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Thank you!

