Navigating a Food Safety Assessment: Purpose, Data Collection & Considerations

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MEAT INDUSTRY FOOD SAFETY CONFERENCE

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Food Safety Assessments Process Overview

- PHRE
  - Initiation
    - Food Safety Incident
    - PHR violation
    - General NR trend/concern from FSIS
  - Analysis
  - Assessment

- FSA
  - Entrance
  - Discovery Phase
  - Report
  - Outcomes

Relevant Directives – In sequential order

- FSIS Directive 5100.5 - Public Health Regulations and FSIS Response to Elevated Public Health Regulation Non-compliance Rates
- FSIS Directive 5100.4 – Public Health Risk Evaluation Methodology
- FSIS Directive 5100.1 – Food Safety Assessment Methodology
- FSIS Directive 5100.3 – Administrative Enforcement Action Decision-Making and Methodology

Public Health Regulations

- Original Question: How can the Agency use the data it collects daily at establishments to better focus inspection resources to better protect public health?
  - Define adverse public health outcomes at establishments
  - Determine when adverse public health outcomes occur
  - Look at previous 3 months of data to see which of the curated regulations have non-compliances that were identified at the establishment
  - Rank the occurs of these NRs based on co-occurrence with adverse situations
  - Those NRs of those regulations become PHRs

Public Health Risk Evaluations

When is a PHRE performed?

- For-Cause
  - Positive result for adulterating pathogen
  - Associated with an outbreak
  - Exceed PHR non-compliance cut-points
- Routine
  - New Grant of Inspection
  - Other factors that may increase public health risk

Public Health Risk Evaluations

Who performs an PHRE?

- Enforcement, Investigation, and Assessment Officers (EIAO)
  - Inspection personnel that are assigned to the District Office
  - Varied backgrounds: Veterinarians, people with advanced degrees, or inspection personnel with field experience and college degrees in food safety/public health
  - Training: Inspection Methods, EIAO training
- District Case Specialist may assist

Public Health Risk Evaluations

What is considered?

- Review of PHIS data – tasks performed, NRs, MOIs, sampling results*
- Customer Complaints received by FSIS
- Other FSIS generated data (i.e. WGS of pathogens, etc)*
- FDA sampling results*
- Enforcement Actions*
- Discussion with IPP and FLS

Public Health Risk Evaluations

What are the possible outcomes?

- EIAOs can recommend to DDM/DM:
  1) Conduct and FSA to further investigate into possible vulnerabilities,
  2) Take an administrative enforcement action, or
  3) Take no action

- PHRE is an internal document and is not shared outside the agency

Food Safety Assessment

Purpose: To verify if Hazard Analysis and Critical Control Point systems are validated and implemented effectively

- Performed by Enforcement, Investigation, Assessment Officer (EIAO)
- Originally designed to evaluate an establishments full food safety plan every 4 -5 years.
- Modified to shorten the process and focus on a few elements of concern in an establishment's food safety plan
- All FSAs performed after a PHRE is completed
  - PHRE informs the need for sample collection and scope of the FSA

Entrance Conference

- Conducted by the EIAO ideally with the FLS and IPP in attendance
- Explain:
  - FSA process
  - Reason for the FSA
  - Scope of the FSA
  - Possible Outcomes
  - Intended work schedule
  - Types of records/data to be examined

Things to Consider Prior to Entrance Conference

- Work space – consider where the EIAO (and additional personnel, if applicable) will be "officed." Some like to be near or in the same room with establishment representation, and some prefer a quiet space on their own.
- Be prepared with:
  - Establishment work schedule (EIAO will want to observe things on multiple shifts, perhaps multiple times)
  - Relevant records, organized and readily available for viewing
  - Validation support (studies, articles, in plant data, etc)
  - Floor personnel should be prepared to demonstrate the tasks they perform
  - Review the FSA tools beforehand to understand what will be looked at

FSA Tools

- EIAOs use a set of tools to help in the FSA process:

https://www.fsis.usda.gov/inspection/compliance-guidance/food-safety-assessments-tools

Data Collection – Initial Phase

- Review Flowcharts and HACCP plans of relevant sections
- Tour the establishment to collect initial observational data
- Review
  - Hazard Analysis
  - Critical control points
  - Supporting documentation

Data Collection – In Depth Program Reviews

- Prerequisite programs
- Sanitation SOPs
- Sampling Programs

Data Collection – In Depth Program Reviews

- Prerequisite programs – validation, records, direct observation
- Sanitation SOPs – observation of pre op, less than daily sanitation, review of procedures, noncompliance trend analysis
- Sampling Programs – direct observation of sampling and support for methods (both collection and laboratory)

Data Collection – Direct Observations

- Is the establishment implementing their food safety plan components as written?
  - SSOP
  - General HACCP
  - Slaughter
  - Further Processing

Data Collection – Direct Observations

- Is the establishment implementing their food safety plan components as written?
  - Whatever your programs say, you must be doing!
  - Example: If the program states "allow the sample to sit for 3 minutes" and you let it sit 2 min 50 sec, or 3 min 10 sec – you may be questioned if the sample is still valid or if results have been impacted by the different time
  - Programs should be designed to function without being unnecessarily restrictive (does it matter if you use a blue glove or a black glove?)
  - Make sure all personnel are trained and authorized to perform the function

Data Collection – Records Review

- Is the establishment recording required documentation routinely?
- Are there recorded deviations?
  - What is the documentation on how the establishment responded to deviations?
  - What were the corrective actions?
  - Were they effective?

Data Collection – Records Review

- Review past records and address any errors or unresolved issues
- Review past investigations and corrective actions – if there are any gaps, address them and ensure preventive measures have been effective
- Remember, this is likely the first time the EIAO has been to your establishment. They are not familiar with your processes and programs. Any documentation needs to be clearly understood by someone with no prior knowledge of the situation!

Data Collection – Validation Documents

- Does the establishment have the appropriate scientific validation documents to support their food safety plans?
- Does the establishment have appropriate technical support for their food safety plans?
- Does the HACCP data support that they are effective and appropriate?

Data Collection – Validation Documents

- Make sure your process parameters are the same as when validation was performed
- If you are not following or monitoring all critical parameters in your support, you MUST have support for why
- Repetitive failures must have documentation for why the CCP/PRP is still functioning as intended without modifications

Analysis and Recommendations

- EIAO will use their observations to answer the questions in the FSA tool
- EIAO will develop recommendations as an outcome
  - No Further Action – No significant issues found
  - Issuance of NRs – Noncompliances identified – In conjunction with FLS and IPP these NRs will be put into PHIS
- Enforcement Action – Significant issues found (may include NRs)
  - Notice of Intended Enforcement
  - Notice of Suspension
- If at any time an EIAO identifies conditions that support an immediate suspension of inspection, the EIAO will stop the process and contact the District Office

Exit Conference

- EIAO will schedule an exit conference with the establishment after the DO reviews the FSA findings
  - Describe findings to the establishment
  - Describe basis for NRs and any enforcement actions
  - Provide copy of draft or final FSA

Exit Conference

- If you receive a NOIE or Suspension, do not delay in contacting your outside resources. You will have a short period of time to respond.
- You will have a verification plan assigned following acceptance of your corrective actions – it is essential that you comply and meet the expectations outlined

An Ounce of Prevention…..

- The best way to handle an FSA is not to trigger one – continuously scrutinize your programs, trust but verify, and modify when necessary, based on your data and trends
- No one looks forward to an FSA, but looking backward is key to recognizing and correcting any issues before the EIAO points them out to you – surprises during an FSA are not fun!

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Survey

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